

EXHIBIT 6

In The Matter Of:

In Re: CR Bard 200

Daniel Elliott M.D., Vol. II

November 16, 2014

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TIFFANY ALLEY
GLOBAL REPORTING
AND VIDEO

IN THE UNITED STATES DISTRICT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C.R. BARD, INC.,
PELVIC REPAIR SYSTEM PRODUCTS
LIABILITY LITIGATION

THIS DOCUMENT RELATES TO ALL
CASES IN MDL NO. 2187 AND
SPECIFICALLY TO:

ROSAIDA ALONSO,
Plaintiff, Civil Action File
No. 2:14-cv-07112
vs.
C.R. BARD, INC.,
Defendant.

PATRICIA BOLYARD, et al.,
Plaintiffs, Civil Action File
No. 2:12-cv-00126
vs.
C.R. BARD, INC.,
Defendant,

MARTINA WHEELER,
Plaintiff, Civil Action File
No. 2:12-cv-04580
vs.
C.R. BARD, INC.,
Defendant.

VOLUME II
The videotaped deposition of DANIEL S. ELLIOTT, M.D.,
November 16, 2014
Wexler Wallace, 55 West Monroe Street, Suite
3300, Chicago, Illinois, commencing at 8:54 a.m.
Reporter: Jennifer L. Bernier

In Re: CR Bard 200

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<p>1 APPEARANCES:</p> <p>2 AYLSTOCK, WITKIN, KREIS & OVERHOLTZ, PLLC 3 MS. P. ANN GAYLE 4 MR. BRANDON S. MORRIS 5 17 East Main Street 6 Suite 200 7 Pensacola, Florida 32502 8 Phone: (850) 202-1010 9 E-mail: agayle@awkolaw.com 10 bmorris@awkolaw.com</p> <p>11 On behalf of the Plaintiffs;</p> <p>12 REED SMITH 13 MS. MELISSA GEIST 14 136 Main Street 15 Suite 250 16 Princeton Forrestal Village 17 Princeton, New Jersey 08540 18 Phone: (609) 514-5978 19 E-mail: Mgeist@reedsmitth.com 20 On behalf of the Defendant.</p> <p>21 ALSO PRESENT: 22 John Doody, Videographer</p> <p>23 * * * * *</p> <p>24</p>	<p>Page 473</p> <p>1 VIDEO TECHNICIAN: We're now on the record. The 2 time is approximately 8:51 a.m. 3 This is the beginning of Disc 1, Volume 2, of 4 the video deposition of Dr. Daniel S. Elliot. 5 Will counsel please identify yourselves for 6 the record and state who you represent. 7 MS. GAYLE: Patty Ann Gayle appearing for the 8 plaintiffs, Wheeler, Alonso, and Bolyard, out of 9 the firm of Aylstock Witkin in Pensacola, 10 Florida. 11 MR. MORRIS: Brandon Morris for the Plaintiffs from 12 Aylstock, Witkin, Kreis & Overholtz. 13 MS. GEIST: Melissa Geist from Reed Smith for the 14 defendant C.R. Bard. 15 VIDEO TECHNICIAN: Would the court reporter remind 16 the witness he's still under oath? 17 THE REPORTER: Sir, you understand you're still 18 under oath? 19 THE WITNESS: I do. 20 (Witness previously sworn.) 21 WHEREUPON: 22 DANIEL S. ELLIOTT, M.D., 23 called as a witness herein, having been previously duly 24 sworn, was examined and testified further as follows: 25 DIRECT EXAMINATION (continued)</p>																																
<p>1 I N D E X</p> <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; width: 50%;">WITNESS</th> <th style="text-align: right; width: 50%;">PAGE</th> </tr> </thead> <tbody> <tr> <td>DANIEL S. ELLIOTT, M.D.</td> <td></td> </tr> <tr> <td>Examination by Ms. Geist</td> <td style="text-align: right;">476</td> </tr> <tr> <td>Examination By Ms. Gayle</td> <td style="text-align: right;">747</td> </tr> <tr> <td colspan="2" style="text-align: center;">E X H I B I T S</td> </tr> <tr> <td colspan="2" style="text-align: center;">ELLIOTT DEPOSITION EXHIBITS</td> </tr> <tr> <td>No. #29 Alonso Report</td> <td style="text-align: right;">477</td> </tr> <tr> <td>No. #30 AP IFU</td> <td style="text-align: right;">509</td> </tr> <tr> <td>No. #31 Suarez Op Report</td> <td style="text-align: right;">559</td> </tr> <tr> <td>No. #33 Wheeler Report</td> <td style="text-align: right;">608</td> </tr> <tr> <td>No. #34 Wheeler Report</td> <td style="text-align: right;">641</td> </tr> <tr> <td>No. #35 Bolyard Report</td> <td style="text-align: right;">656</td> </tr> <tr> <td>No. #36 Marlex MSDS</td> <td style="text-align: right;">717</td> </tr> <tr> <td>No. #37 '93 Marlex MSDS</td> <td style="text-align: right;">717</td> </tr> <tr> <td>No. #38 '97 Marlex MSDS</td> <td style="text-align: right;">717</td> </tr> <tr> <td>No. #39 Melkerson Letter</td> <td style="text-align: right;">729</td> </tr> </tbody> </table> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	WITNESS	PAGE	DANIEL S. ELLIOTT, M.D.		Examination by Ms. Geist	476	Examination By Ms. Gayle	747	E X H I B I T S		ELLIOTT DEPOSITION EXHIBITS		No. #29 Alonso Report	477	No. #30 AP IFU	509	No. #31 Suarez Op Report	559	No. #33 Wheeler Report	608	No. #34 Wheeler Report	641	No. #35 Bolyard Report	656	No. #36 Marlex MSDS	717	No. #37 '93 Marlex MSDS	717	No. #38 '97 Marlex MSDS	717	No. #39 Melkerson Letter	729	<p>Page 474</p> <p>1 BY MS. GEIST: 2 Q. Good morning, Dr. Elliot. 3 A. Good morning. 4 Q. We spent a considerable part of yesterday 5 together, and I don't need to remind you of the rules of 6 the deposition, I assume. You understand it's a 7 question-and-answer period. We need to be careful not 8 to talk over one another. And if I ask you anything you 9 don't understand, will you let me know? 10 A. Yes. 11 Q. So I can rephrase the question. And I think 12 we worked pretty well yesterday under those rules? 13 A. Yes. 14 Q. Do you agree? Okay. 15 A. Yes. 16 MS. GAYLE: And, Counsel, before you get started, 17 just for the record, it's our position that you're going 18 to take no more than two hours per case today on each of 19 these individual cases. 20 MS. GEIST: Well, and let me just add that we don't 21 have any formal agreement. I'm not going to limit 22 myself to time. I'm going to do my best to be as 23 efficient as possible. I know we all want to catch 24 flights. So let me -- let me start by asking the doctor 25 if a couple of things are agreeable, and then we'll see</p>
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<p style="text-align: right;">Page 477</p> <p>1 if we can be efficient.</p> <p>2 BY MS. GEIST:</p> <p>3 Q. Dr. Elliott, yesterday you provided testimony</p> <p>4 with respect to your generic opinions that you're</p> <p>5 offering in this litigation, correct?</p> <p>6 A. Correct.</p> <p>7 Q. And you understand, today, that we're focusing</p> <p>8 on the specific opinions you've provided in three</p> <p>9 reports for three separate plaintiffs, correct?</p> <p>10 A. Yes.</p> <p>11 Q. Would you agree with me, Doctor, that some of</p> <p>12 the opinions in your report for the three separate</p> <p>13 plaintiffs are identical in certain respects?</p> <p>14 A. In certain respects they're going to be, yeah,</p> <p>15 very similar, if not identical.</p> <p>16 (Elliott Deposition Exhibit No. 29</p> <p>17 was marked for identification.)</p> <p>18 BY MS. GEIST:</p> <p>19 Q. Okay. So, for example, if you look at what</p> <p>20 I've already marked as Exhibit 29 to your deposition,</p> <p>21 that's a case-specific expert report for Rosaida Alonso?</p> <p>22 A. Correct.</p> <p>23 Q. If you look at page 8 of that report, in the</p> <p>24 first full paragraph, it says, Set out in my general</p> <p>25 causation expert report several characteristics of the</p>	<p style="text-align: right;">Page 479</p> <p>1 A. Yes, I do.</p> <p>2 Q. Similarly, by my review, that section of the</p> <p>3 report, pages 8 through 11, when you talk about the</p> <p>4 risks that should have been placed in the IFU, that is</p> <p>5 identical to the information and opinions you've</p> <p>6 provided in the reports for Mrs. Wheeler and</p> <p>7 Mrs. Bolyard, correct?</p> <p>8 A. Yes.</p> <p>9 Q. So, again, if I can explore the basis for your</p> <p>10 opinions here in Mrs. Alonso's case, we don't need to go</p> <p>11 through the same information and I don't need to ask you</p> <p>12 the same questions in the other two cases, do you agree?</p> <p>13 MS. GAYLE: It's our -- before I let him answer</p> <p>14 that, Counsel, it's our position that these generic</p> <p>15 types of opinions that are in these three are -- as</p> <p>16 you've said, they are similar, but they also go back to</p> <p>17 his general opinions from yesterday. And so it's our</p> <p>18 position that they really don't need to be rehashed at</p> <p>19 all because they're part of his general opinions.</p> <p>20 They're just incorporated into these case reports.</p> <p>21 MS. GEIST: Well, the only thing I'll say about</p> <p>22 that is, I am entitled to explore them. They're not set</p> <p>23 forth as just general opinions. In the report itself,</p> <p>24 it specifically talks about how they apply to each</p> <p>25 individual case.</p>
<p style="text-align: right;">Page 478</p> <p>1 Marlex polypropylene mesh render it inherently unsafe</p> <p>2 for use in Ms. Alonso. And then you describe five</p> <p>3 different reasons why the Marlex polypropylene mesh is</p> <p>4 inherently unsafe for use in Ms. Alonso.</p> <p>5 And this paragraph is identical in the reports</p> <p>6 you have also rendered for the two other plaintiffs</p> <p>7 we're going to speak about today, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Okay. So what I'm trying to do is see if we</p> <p>10 have an agreement that I don't need to reask or go</p> <p>11 through these same issues with you in the cases for</p> <p>12 Mrs. Wheeler and Mrs. -- I want to make sure I got her</p> <p>13 name right -- Bolyard, B-O-L-Y-A-R-D. So anything I ask</p> <p>14 you here, when we talk about Ms. Alonso, can we apply</p> <p>15 your answers to the other two cases?</p> <p>16 A. Yes.</p> <p>17 Q. And so then we don't have to repeat and try to</p> <p>18 be efficient and quick as possible?</p> <p>19 A. Absolutely.</p> <p>20 Q. Okay. Similarly, you have some opinions, in</p> <p>21 each of your three case-specific expert reports, that</p> <p>22 deal with the risks that you will opine Bard knew about</p> <p>23 and, therefore, should have put in the IFU. And that</p> <p>24 section of your Alonso report is pages 8 through 11. Do</p> <p>25 you see that, Doctor?</p>	<p style="text-align: right;">Page 480</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Is that correct, Doctor?</p> <p>3 A. Correct.</p> <p>4 Q. So, anyway, the point is, I don't want to have</p> <p>5 to reask you the same types of questions in the other</p> <p>6 two cases. So do you agree whatever I ask you relating</p> <p>7 to the information in the IFU, et cetera, can apply to</p> <p>8 the other two cases; is that fair?</p> <p>9 A. I agree with that unless I think of something</p> <p>10 that does not quite correlate; but I agree with you,</p> <p>11 yeah.</p> <p>12 Q. That's fine. Thank you. Doctor, yesterday,</p> <p>13 when we began your deposition relating to your generic</p> <p>14 opinions, I asked you if you could tell me how much time</p> <p>15 you spent on the cases. Do you remember that?</p> <p>16 A. Yes.</p> <p>17 Q. And you were unable to give me any information</p> <p>18 or any documents really into how much time you spent on</p> <p>19 the cases, correct?</p> <p>20 A. Correct.</p> <p>21 Q. I assume you didn't go back and look into that</p> <p>22 so you could tell me more information today?</p> <p>23 MS. GAYLE: Object to form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. That is correct.</p>

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<p style="text-align: right;">Page 481</p> <p>1 Q. And you don't have any invoices or paperwork 2 or correspondence with you that would help us understand 3 how much time you spent in formulating your generic and 4 case-specific opinions?</p> <p>5 A. I do not have those with me, no.</p> <p>6 Q. Did I also understand you correctly from 7 yesterday that you've never broke out separately how 8 much time you've spent on Mrs. Alonso's case 9 specifically separate from your generic opinions; is 10 that right?</p> <p>11 A. No. There is an itemized invoice sent to 12 Mr. Anderson's office of each individual and how much 13 time was spent reviewing medical records, IME exams, 14 those types of things.</p> <p>15 Q. So -- and Mr. Anderson is an attorney 16 representing the plaintiffs in this litigation?</p> <p>17 A. I don't know how to answer that. He was 18 the -- he is the one that I've been told to send my 19 invoice to, to his office, his paralegal.</p> <p>20 Q. So just so I understand, when you invoice, do 21 you provide a separate invoice for your generic work and 22 then a separate invoice for each individual plaintiff's 23 case that you work on and provide opinions for?</p> <p>24 A. There will be a section broken down into 25 generic work, review of documentation, internal</p>	<p style="text-align: right;">Page 483</p> <p>1 submitted.</p> <p>2 Q. Okay. You don't have an estimate or an 3 approximation for me how much time you spent in forming 4 your opinions on Mrs. Alonso's case as you sit here 5 today?</p> <p>6 A. No, I do not.</p> <p>7 MS. GEIST: Okay. And, Counsel, I would just make 8 a formal request for the invoices that Dr. Elliott has 9 submitted to Mr. Anderson's office for all of his work 10 done in formulating his generic opinions as well as his 11 opinions in the three specific plaintiffs' cases we're 12 discussing here today. Thank you.</p> <p>13 BY MS. GEIST:</p> <p>14 Q. How did you go about preparing and formulating 15 your opinions specific to Mrs. Alonso?</p> <p>16 A. Initially, medical records were sent to me 17 electronic -- I don't have any paper records -- of all 18 of the medical records pertaining to her care prior and 19 after her initial surgery. So I reviewed those and then 20 also reviewing the pertinent literature that would come 21 about through my research on her case.</p> <p>22 Q. And if we refer to your expert report that 23 we've marked as Exhibit 29, that's the report that you 24 provided for Mrs. Alonso; is that correct, Doctor?</p> <p>25 A. Correct.</p>
<p style="text-align: right;">Page 482</p> <p>1 documents, medical records -- not records, excuse me -- 2 manuscripts. That will be in the general. And then it 3 will be broken down into the various different 4 individuals, how much time was spent reviewing their 5 medical records, how much time was spent during the IME.</p> <p>6 Q. So it's -- it's all in the same invoice, but 7 there is a separate section for Mrs. Alonso. Is that 8 what I am hearing from you, Doctor?</p> <p>9 A. That would be -- that would be correct.</p> <p>10 Q. Okay.</p> <p>11 A. But just because Alonso, or whomever, has a 12 certain amount of allotted time, that does not 13 necessarily correlate to that was the only time spent on 14 the individual because the general review of literature, 15 everything, will actually correlate to them, these 16 individuals, too.</p> <p>17 Q. Your general review of literature helped you 18 inform your opinions about each specific case; is that 19 what you're telling me?</p> <p>20 A. That is correct.</p> <p>21 Q. Okay. So for Mrs. Alonso, specifically, can 22 you tell me how much time you spent on her case?</p> <p>23 A. No, I can't, because I don't have those 24 records. That would be retrievable through 25 Mr. Anderson's office and the invoices that were</p>	<p style="text-align: right;">Page 484</p> <p>1 Q. And that has a number of attachments to it 2 starting with Exhibit A. And that's your CV, correct?</p> <p>3 A. Correct.</p> <p>4 Q. And the only updates that need to be made to 5 that CV are a couple of things you noted to me yesterday 6 when we discussed your generic opinions, correct?</p> <p>7 A. Correct.</p> <p>8 Q. And then Exhibit B also provides your fee 9 schedule and testimony history, and that's the same as 10 you provided to us in your generic report, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And then Exhibit C has a list of materials 13 reviewed and relied upon, and you incorporate your 14 general report here as well, correct?</p> <p>15 A. Correct.</p> <p>16 Q. And with respect to that general report, you 17 provided us, a day or two before your deposition 18 yesterday, with an updated literature review list or 19 bibliography, correct?</p> <p>20 A. Well, I don't know when it arrived to you. I 21 sent it to the lawyers on Monday or Tuesday, something 22 like that.</p> <p>23 Q. Okay. But I assume you wish to incorporate 24 your updated bibliography here in Mrs. Alonso's case?</p> <p>25 A. Correct.</p>

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<p style="text-align: right;">Page 485</p> <p>1 Q. And then, if you look at the second and third 2 page of what is Exhibit C to your report in 3 Mrs. Alonso's case, that appears to list what I will 4 call the case-specific records for Mrs. Alonso?</p> <p>5 A. Yeah. These are the medical records that I 6 reviewed pertaining to her care.</p> <p>7 Q. You also have listed here depositions as well, 8 correct?</p> <p>9 A. Correct. Yeah. And I assume -- and there's 10 four -- four depositions. So it's medical records and 11 depositions.</p> <p>12 Q. And who is Mr. Gill?</p> <p>13 A. Oh, Mr. Gill. I would have to go back and 14 look at the records of who Mr. Gill is. I can't recall.</p> <p>15 Q. And how about Dr. Juan Suarez? Who is that?</p> <p>16 A. Suarez was the implanting surgeon.</p> <p>17 Q. And how about Dr. Carlos Medina?</p> <p>18 A. Carlos Medina is the surgeon who took care of 19 the complications, some of the complications, I should 20 say.</p> <p>21 Q. And on Exhibit C, on pages 2 and 3, is this a 22 complete list of all of the case-specific records you 23 reviewed in reaching your opinions with respect to 24 Mrs. Alonso?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 487</p> <p>1 are listed there on page 3 of Exhibit C? Did you review 2 those depositions in their entirety or were you provided 3 with excerpts only?</p> <p>4 A. Their entirety, all four. And that would 5 pertain to everybody else, Bolyard and Wheeler as well.</p> <p>6 Q. Okay. Perfect. So I can just go ahead and 7 use your answers for those --</p> <p>8 A. Extrapolate.</p> <p>9 Q. -- cases as well? Thank you for that. Are 10 all of your opinions with respect to Mrs. Alonso's case 11 set forth here, Doctor, in your expert report?</p> <p>12 A. Yes, they are, unless new material were 13 provided to me. But, yes.</p> <p>14 Q. As of now, this is what I would refer to as 15 your complete analysis of the case?</p> <p>16 A. That is correct.</p> <p>17 Q. You mentioned already a couple of times an 18 IME. So let me ask you about that. Did you perform an 19 independent medical exam for Mrs. Alonso?</p> <p>20 A. Yes, I did.</p> <p>21 Q. And did you also do that for Mrs. Wheeler 22 and --</p> <p>23 A. Bolyard.</p> <p>24 Q. -- Mrs. Bolyard?</p> <p>25 A. Yes, I did.</p>
<p style="text-align: right;">Page 486</p> <p>1 Q. Were all of these records sent to you 2 initially when you were asked to do an expert report in 3 this case?</p> <p>4 A. I can't recall that. I received large batches 5 of medical records. There may be a possibility that I 6 went through and reviewed and found a notation to a 7 certain study and I requested it. I don't recall with 8 this.</p> <p>9 Q. Do you know, sitting here today, whether you 10 asked for any additional records to help inform your 11 opinions with respect to Mrs. Alonso's case?</p> <p>12 A. I can't say specifically to Mrs. Alonso. I 13 had requested further records of other doctors. It 14 mentions there would be clinic notes, but it mentioned I 15 saw Dr. So-and-so. And I didn't have that, so I'd 16 request it. I cannot say in, actually, Ms. Alonso I did 17 that, though.</p> <p>18 Q. Did -- did you review, in their entirety, all 19 of the records listed here on pages 2 and 3 of Exhibit C 20 to your report?</p> <p>21 A. Yes. And I believe with Ms. Alonso that came 22 out to something like 1925 pages.</p> <p>23 Q. And you reviewed every page?</p> <p>24 A. Yes, I did.</p> <p>25 Q. And how about the deposition transcripts that</p>	<p style="text-align: right;">Page 488</p> <p>1 Q. Thank you. For some reason, that 2 pronunciation is going to give me trouble all day, so 3 I'm going to write it down.</p> <p>4 And my understanding, Doctor, from reviewing 5 your reports in those three plaintiffs' cases, is that 6 you saw all three women on the same day; is that right?</p> <p>7 A. Correct, on October 4th, 2014.</p> <p>8 Q. And where did those IMEs take place?</p> <p>9 A. Nashville.</p> <p>10 Q. Nashville, Tennessee?</p> <p>11 A. Correct.</p> <p>12 Q. Why Nashville, Tennessee?</p> <p>13 A. That's -- that's where I was told they were 14 being arranged.</p> <p>15 Q. Who -- strike that.</p> <p>16 At what facility in Nashville, Tennessee?</p> <p>17 A. It was a -- there is an OB/GYN office that it 18 was taken place in. If you would like the exact 19 address, I could give that to you.</p> <p>20 Q. It was a doctor's office?</p> <p>21 A. Correct.</p> <p>22 Q. Do you know the name of the OB/GYN or the name 23 of the practice?</p> <p>24 A. I don't know the name of whose office it is.</p> <p>25 It was Legacy OB/GYN of Tennessee, actually, in Smyrna,</p>

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<p style="text-align: right;">Page 489</p> <p>1 which is, S-M-Y-R-N-A, which is a suburb in Nashville.</p> <p>2 Q. You told me yesterday that you bill for your</p> <p>3 time at the rate of \$700 an hour; is that right?</p> <p>4 A. That is correct.</p> <p>5 Q. So did you bill for your travel to Nashville,</p> <p>6 Tennessee, to perform the IMEs?</p> <p>7 A. Correct.</p> <p>8 Q. And that was at the 700-dollar-an-hour rate?</p> <p>9 A. Correct. Everything I do is at \$700 an hour.</p> <p>10 Q. Okay. So, for all three cases, however much</p> <p>11 time you spent doing the IME, that was at the</p> <p>12 700-hundred-dollar-an-hour rate?</p> <p>13 A. That is correct.</p> <p>14 Q. And then your return travel to Minnesota was</p> <p>15 at the same rate?</p> <p>16 A. Correct.</p> <p>17 Q. How much time did you spend with Mrs. Alonso?</p> <p>18 A. Each -- each individual face-to-face time was,</p> <p>19 roughly, 45 minutes, but that's not counting, obviously,</p> <p>20 the time reviewing the records and things, but</p> <p>21 face-to-face time and exam.</p> <p>22 Q. So that's the same, roughly, 45 minutes for</p> <p>23 Mrs. Wheeler and Mrs. Bolyard?</p> <p>24 A. That is an estimate, a fairly accurate</p> <p>25 estimate. I can't say exactly 45 minutes with each one.</p>	<p style="text-align: right;">Page 491</p> <p>1 an operative note. So, again, there is no correlation</p> <p>2 between volume and time. So I can't answer that</p> <p>3 question.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. Well, would you agree with me that</p> <p>6 Mrs. Bolyard has a more extensive and complex medical</p> <p>7 history than Mrs. Alonso and Mrs. Wheeler?</p> <p>8 A. I think her past medical history is more</p> <p>9 complicated. I deal with this on a daily basis in my</p> <p>10 practice. So as far as complicated, they're all</p> <p>11 complicated.</p> <p>12 Q. Did you need to conduct the IMEs in order to</p> <p>13 reach the opinions in Mrs. Alonso's case and</p> <p>14 Mrs. Wheeler's case and Mrs. Bolyard's case?</p> <p>15 A. Oh, I think it's essential. In this type of</p> <p>16 thing, you have to be able to do an exam. It's not like</p> <p>17 you can do a blood test or an X-ray to know. You have</p> <p>18 to actually do a physical exam. And much to the</p> <p>19 patient's chagrin, you have to also do a pelvic exam.</p> <p>20 And so, yes, in my opinion, my strong opinion,</p> <p>21 it was essential to do an exam. Without an exam, you</p> <p>22 can't make an accurate diagnosis.</p> <p>23 Q. So you couldn't make an accurate diagnosis or</p> <p>24 formulate your opinions in any of the cases without</p> <p>25 conducting the IME; is that what you're telling me?</p>
<p style="text-align: right;">Page 490</p> <p>1 Some were a little bit more. Some were a little bit</p> <p>2 less.</p> <p>3 Q. Do you remember who took the longest of the</p> <p>4 three plaintiffs?</p> <p>5 A. I do not recall.</p> <p>6 Q. Do you remember whether you had to spend more</p> <p>7 time with Mrs. Alonso compared to Mrs. Wheeler compared</p> <p>8 to Mrs. Bolyard?</p> <p>9 A. I do not recall any of them taking more or</p> <p>10 less time. I was not focused on that. Reviewing their</p> <p>11 medical records at times could take considerably more,</p> <p>12 considerably less, depending upon the volume of records.</p> <p>13 Q. The volume of records for each of these</p> <p>14 plaintiffs is different. Fair summary?</p> <p>15 A. That's correct.</p> <p>16 Q. Mrs. Bolyard, for example, has a more</p> <p>17 extensive and complicated medical history than</p> <p>18 Mrs. Alonso and Mrs. Wheeler?</p> <p>19 MS. GAYLE: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. I can't necessarily say. The volume of</p> <p>22 records does not correlate to the complexity. Sometimes</p> <p>23 I would be provided 200 pages of nursing notes which had</p> <p>24 very little material to it, but it took time and pages.</p> <p>25 Sometimes I would spend an hour or two on one page like</p>	<p style="text-align: right;">Page 492</p> <p>1 MS. GAYLE: Object to form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No. What I'm saying is, I can review the</p> <p>4 outside records, review the other individual's exams,</p> <p>5 formulate somewhat of an opinion of what other people</p> <p>6 think. However, I'm going to keep an open mind because,</p> <p>7 in my practice, where I practice at the tertiary care</p> <p>8 center, I'm always keeping an open mind and I have to do</p> <p>9 an exam to prove it for myself. I do this daily. So</p> <p>10 it's not like an individual who might not see this very</p> <p>11 often.</p> <p>12 So the IME would be further -- the physical</p> <p>13 exam, the interaction with the individual, talking to</p> <p>14 them is a major part of coming to a conclusion, but it's</p> <p>15 not everything.</p> <p>16 Q. But you're not going to reach your final</p> <p>17 conclusion and analysis until you do that IME, correct?</p> <p>18 MS. GAYLE: Objection. Asked and answered.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No. I would say that I will form ideas,</p> <p>21 concepts, and a differential diagnosis based upon the</p> <p>22 medical records and then determine if my physical exam</p> <p>23 agrees or disagrees with what others had said.</p> <p>24 Q. So you told me that you did the IME for the</p> <p>25 three plaintiffs on October 14th, 2014, correct?</p>

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<p>1 A. October 4th.</p> <p>2 Q. I thought you said October 14th. Is it the 3 4th?</p> <p>4 A. I'm going off of -- I don't recall exactly 5 which day. I have to go off of what I wrote down here. 6 And I have written down here October 4th. I would have 7 to go through whatever date I state in here is the date. 8 Because on page 4 of Alonso, I say October 4th. Yeah, I 9 say -- yeah, it's October 4th.</p> <p>10 Q. Okay. That's fine. I thought you told me 11 October 14th, which is why I was asking you.</p> <p>12 A. I may have said that. That would be 13 incorrect. October 4th is the correct date.</p> <p>14 Q. So my question is, so you performed your IME 15 before you signed your expert reports in each of the 16 three cases?</p> <p>17 A. That is correct.</p> <p>18 Q. And Mrs. Alonso's report is dated October 9th, 19 2014, correct?</p> <p>20 A. That is correct.</p> <p>21 Q. And that's your signature there, Dr. Elliott?</p> <p>22 A. That is an electronic signature, yes.</p> <p>23 Q. Okay. But this is a true copy of your expert 24 report in the case, correct --</p> <p>25 A. That is correct.</p>	<p>Page 493</p> <p>1 taking, it was just myself and the patient. No one else 2 was in the room. I did not allow anybody in the room.</p> <p>3 Q. Did you have a nurse or a physician's 4 assistant or anybody like that?</p> <p>5 A. For just the hyst- --</p> <p>6 MS. GAYLE: Excuse me. Just let him finish the 7 question so y'all don't talk over each other.</p> <p>8 MS. GEIST: Sure.</p> <p>9 MS. GAYLE: -- for the court reporter's sake.</p> <p>10 MS. GEIST: No. I apologize.</p> <p>11 BY THE WITNESS:</p> <p>12 A. For just the history taking, confirmation of 13 what I had reviewed with the patient, I mean, as far as 14 medical records, I went over my medical records, my 15 notes, asked the patient did this correlate, did they 16 agree with this? That was just myself and the patient.</p> <p>17 That --</p> <p>18 Q. So --</p> <p>19 A. I'll finish.</p> <p>20 Q. I'm sorry. I'm sorry. I thought you were 21 done.</p> <p>22 A. That's all right. Then when it came to the 23 physical exam, there was a nurse present to act as a 24 chaperone when I did just the physical exam. So I would 25 exit the room. The nurse would come in. This was an</p>
<p>1 Q. -- as you flip through it?</p> <p>2 Did any of your opinions, with respect to 3 Mrs. Alonso, change after you performed the IME?</p> <p>4 A. Not that I recall, no, not specifically.</p> <p>5 Because of what I do on a daily basis, as far as where I 6 work, and I'm used to dealing with this, I'm looking for 7 things that weren't necessarily examined before, like 8 pain over the buttock where obturator -- where the mesh 9 arms could be obturator pain, adductor pain, abductor 10 pain, A-B-D-U-C-T-O-R-S.</p> <p>11 On the physical exam, I'm specifically 12 touching where -- inside the vagina on the midportion.</p> <p>13 So, again, I have an idea because of what I do all of</p> <p>14 the time of what the diagnosis could be. But, again, I</p> <p>15 would say it augmented my knowledge of the patient.</p> <p>16 Q. So you don't recall, with respect to</p> <p>17 Mrs. Alonso's case or Mrs. Wheeler's case or</p> <p>18 Mrs. Bolyard's case, whether you needed to amend or</p> <p>19 change your initial opinions that you formed about each</p> <p>20 of the cases after the IME was conducted?</p> <p>21 A. I don't recall doing that on either -- any of 22 these three individuals.</p> <p>23 Q. Who was present during the IMEs that you</p> <p>24 performed for each of the plaintiffs?</p> <p>25 A. For the interaction, the initial history</p>	<p>Page 494</p> <p>1 employee of the OB/GYN clinic. I did not -- I had never 2 met her before. She would get the patient ready. I 3 would come back and then I would do the physical exam 4 with the nurse there. I would exit. The nurse would 5 get the patient dressed. I would come back, go over a 6 few things, and that was it.</p> <p>7 Q. Are you finished?</p> <p>8 A. Yes.</p> <p>9 Q. I apologize. Sometimes I jump in a little too</p> <p>10 quickly.</p> <p>11 A. No worries.</p> <p>12 Q. Were there any lawyers present at any time</p> <p>13 during any of your IMEs of each of the three plaintiffs?</p> <p>14 A. I cannot speak if they had been out in the 15 waiting room. I did not see anybody. I did not allow 16 anyone in the room, no family members. There was only 17 one time that a family member requested to come back. I 18 told them, no, and I don't know if it was on this one or 19 not. It could have been on another individual. So 20 bottom line, no. I didn't see anybody.</p> <p>21 Q. So, during the time that you took an initial</p> <p>22 history, there wasn't any other person in the room other</p> <p>23 than you and the plaintiff, correct?</p> <p>24 A. At all times, for all individuals, I was the 25 only one there with the patient alone.</p>

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<p style="text-align: right;">Page 497</p> <p>1 Q. And during the actual pelvic and vaginal exam 2 portion of the IME, were there any other physicians 3 present?</p> <p>4 A. No. It was only, at all times for all three 5 individuals, when it came time for the physical exam, 6 there was just myself, the patient, and the nurse. That 7 was it.</p> <p>8 Q. Did you -- were there any other plaintiffs' experts there at the OB/GYN facility on the same day examining women?</p> <p>11 A. No.</p> <p>12 Q. Did you examine any other women on that day other than Mrs. Alonso, Mrs. Wheeler, Mrs. Bolyard who have lawsuits against Bard?</p> <p>15 MS. GAYLE: Object to form. And I'm going to ask that you not answer that. We're not here to talk about any other plaintiffs in this litigation except these three ladies.</p> <p>19 MS. GEIST: So you're instructing the witness not to answer?</p> <p>21 MS. GAYLE: I don't think that it's relevant, Counsel.</p> <p>23 MS. GEIST: I'm just trying to understand your position.</p> <p>25</p>	<p style="text-align: right;">Page 499</p> <p>1 on. I brought that in with my yellow notepad. I took 2 notes. And immediately, at the finish of the IME, I go 3 out. I would put them into an iPad, and then I had the 4 notes shredded. So the actual handwritten notes are 5 gone.</p> <p>6 Q. So you actually took down information that each of the plaintiffs provided to you on a yellow notepad, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And then, after you obtained that information, you put some of it into an iPad?</p> <p>12 A. Correct, into -- into a Word document so that 13 it was legible, understandable, because I take a lot of 14 notes. There could be arrows pointed everywhere. I 15 make it organized so it's not forgotten, immediately put 16 it into a document labeled that specific patient so 17 there is no mistake on the individual, and then get rid 18 of the paper copy.</p> <p>19 Q. And so that was a Word document you're describing?</p> <p>21 A. A Word document saved in Dropbox so it would 22 not be lost, yes.</p> <p>23 Q. You said you shredded the yellow notepad where you took the notes regarding all three women?</p> <p>25 A. Correct. For confidentiality purposes, the</p>
<p style="text-align: right;">Page 498</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Did you examine any other women for whom you did not provide an expert report?</p> <p>4 A. No.</p> <p>5 Q. Did you spend any time with any of the three plaintiffs after the IME?</p> <p>7 A. No. Once I was done with it, no. After that, they left.</p> <p>9 Q. Dr. Elliott, you told me that initially you had a conversation with each of the three plaintiffs and you took a history; is that right?</p> <p>12 A. Correct.</p> <p>13 Q. Did you have them fill out any documents, any forms?</p> <p>15 A. No.</p> <p>16 Q. Did they fill out any paperwork at any point in time during the IME?</p> <p>18 A. No.</p> <p>19 Q. So where did you record the history and information that you were provided from each of the plaintiffs?</p> <p>22 A. I had a notepad, a yellow legal notepad.</p> <p>23 Q. And where is that notepad?</p> <p>24 A. I took notes. I had -- I had my printout of 25 the medical records that I took just the generic notes</p>	<p style="text-align: right;">Page 500</p> <p>1 handwritten notes -- not that anyone would be able to 2 read my writing -- but the handwritten notes were 3 shredded.</p> <p>4 Q. Is there any information that was contained on the yellow notepad that was not put into the Word document?</p> <p>7 A. No. Essentially, everything was transferred over to just a digital copy is all.</p> <p>9 Q. Did anybody ever tell you that you needed to preserve information with respect to your IME of the three plaintiffs?</p> <p>12 MS. GAYLE: Object to form. He did preserve this information.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Yeah. All of the information was preserved. 16 It was put into a logical, legible way. A doctor's 17 handwriting, as you know, tends to be scattered. There 18 are arrows transferred all around, so I wanted to make 19 sure immediately after coming out of the room, when it 20 was fresh in my mind, I put it into a legible, logical 21 document.</p> <p>22 Q. And do you have access to that Word document now?</p> <p>24 A. No. All of those documents then were put into 25 my physical exam notes. My history notes were then put</p>

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<p style="text-align: right;">Page 501</p> <p>1 into the IME, and so they were all just transferred all 2 over.</p> <p>3 Q. So do you still have that Word document, 4 though, for each plaintiff?</p> <p>5 A. Those documents are gone because I don't keep 6 them because then it gets confusing which document is 7 what. So I transferred all of those into my IME, get 8 rid of the old documents, and then I would have this as 9 my official document.</p> <p>10 Q. So if we look at Mrs. Alonso's report 11 beginning on page 4 where it begins, On October 4th, 12 2014, in Nashville, Tennessee, I personally examined 13 Mrs. Alonso?</p> <p>14 A. That is correct.</p> <p>15 Q. Do the notes or the information provided here, 16 is that what came from your Word document which came 17 from your yellow notepad?</p> <p>18 A. Yes.</p> <p>19 MS. GAYLE: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. That is correct.</p> <p>22 Q. Is there anything that you recorded on the 23 yellow notepad or in the Word document that is not 24 contained here in the expert report?</p> <p>25 A. To the best of my knowledge, this is it.</p>	<p style="text-align: right;">Page 503</p> <p>1 Q. And that document no longer exists? 2 A. Correct.</p> <p>3 Q. And neither does the yellow notepad? 4 A. Correct.</p> <p>5 Q. So where, in your report, is all of the 6 information that you recorded during the IME?</p> <p>7 A. It is recorded in, as far as me going through 8 the history, there will be parts of it in there for 9 clarification of dates or feelings, pain, et cetera.</p> <p>10 And then, if you go to page 4, really start at the very 11 top where it says, Currently, Mrs. Alonso is not 12 sexually active due to pain, that would probably be 13 where it actually started. Because currently to me 14 means as of that date, October 4th. And so, when you 15 see a Visual Analog Pain Scale, that is my records, my 16 input.</p> <p>17 Q. Is there anywhere else in the report where the 18 information you obtained via the IME could be found?</p> <p>19 A. Well, in the diagnoses, the physical exam, 20 which is that part here, the differential diagnosis, all 21 of those things.</p> <p>22 Q. Can you be sure, sitting here today, Doctor, 23 that every word and information piece you took down 24 during the IME and recorded on your yellow notepad and 25 put into a Word document is contained here in the expert</p>
<p style="text-align: right;">Page 502</p> <p>1 Q. Are you sure about that?</p> <p>2 A. I just said, to the best of my knowledge, this 3 is it.</p> <p>4 Q. And did you say to me that you deleted the 5 Word document after it was prepared by you?</p> <p>6 A. Yeah. Because it goes all into this note, so 7 there is no reason to keep two documents.</p> <p>8 Q. There is no way of retrieving that document 9 now?</p> <p>10 MS. GAYLE: Just, Counsel, so you're clear, you're 11 asking him to look at a certain section, but then your 12 next question was with regard to the case-specific 13 expert report. And so, just so y'all are both on the 14 same page and I'm not confused, are you talking about 15 that one particular section or that -- or the entire 16 report? I'm confused.</p> <p>17 MS. GEIST: Well, yeah. Sure.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. You tell me, Dr. Elliott, if you can. You 20 told me you recorded certain information on a yellow 21 notepad, and then you took that information and you put 22 it in a Word document for Mrs. Alonso, correct?</p> <p>23 A. Correct.</p> <p>24 Q. And it was actually labeled Rosaida Alonso?</p> <p>25 A. Correct.</p>	<p style="text-align: right;">Page 504</p> <p>1 report for Mrs. Alonso?</p> <p>2 A. To the best of my knowledge, it is. There 3 would be no reason to delete or remove anything. All 4 the notepad and the Word document are for clarification, 5 legibility. And if I see a large number of individuals, 6 as per my habit to keep things organized, I immediately 7 take care of it at that point in time so, again, it's 8 logical so I don't get anything -- make any mistakes.</p> <p>9 Q. During your review of the medical records for 10 Mrs. Alonso, did you take notes as you went through and 11 reviewed those records?</p> <p>12 A. Yes.</p> <p>13 Q. Where are those notes?</p> <p>14 A. Those notes are in here.</p> <p>15 Q. Well, how did you -- how did you take them 16 when you initially looked at the records? What was 17 your -- what was your method?</p> <p>18 A. I go through and, as I make a note of it, like 19 I find -- I document the -- I document the document that 20 I was reviewing, which is in the reliance list. I'll 21 take notes as far as the date of surgery. I'll take 22 quotes out of the operative note, doctor's comments, 23 those types of things.</p> <p>24 Q. So just so I understand, so when you're 25 reviewing the medical records, do you actually highlight</p>

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<p style="text-align: right;">Page 505</p> <p>1 or put comments or do anything to the records 2 themselves?</p> <p>3 A. No.</p> <p>4 Q. Do you take handwritten notes?</p> <p>5 A. Handwritten or electronic notes.</p> <p>6 Q. So do you have handwritten notes somewhere 7 relating to your review of medical records for 8 Mrs. Alonso?</p> <p>9 A. No. Handwritten notes are taken initially.</p> <p>10 Everything I convert over to electronic. Handwritten 11 notes are just for -- because the medical records I get 12 don't necessarily come in any sequence, chronologic 13 sequence. So it's very difficult. I get one year, a 14 next year, and then they're flopped back and forth. So 15 handwritten notes sometimes are just easier to take to 16 start off with and then I convert that to electronic.</p> <p>17 Q. And did you also destroy any handwritten 18 notes you took with respect to the records of 19 Mrs. Alonso?</p> <p>20 MS. GAYLE: Object to form. Mischaracterizes his 21 testimony.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. Did you get rid of those notes?</p> <p>24 MS. GAYLE: Object to form.</p> <p>25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 507</p> <p>1 BY THE WITNESS:</p> <p>2 A. I took -- yeah, I took notation of it, yeah, 3 so of a chronologic sequence, which then I put into the 4 records here.</p> <p>5 Q. And where is the chronologic sequence or other 6 notes that you took with respect to the medical records 7 for Mrs. Alonso, Mrs. Wheeler, and Mrs. Bolyard?</p> <p>8 A. I have a Dropbox account they would be in.</p> <p>9 Q. So is that information accessible and 10 available now?</p> <p>11 A. I would be able to get access to it, yes.</p> <p>12 MS. GEIST: So I'll just make a formal demand and 13 request for that information we just discussed, which is 14 Dr. Elliott's electronic notes regarding his review of 15 the medical records of Mrs. Alonso and Mrs. Wheeler and 16 Mrs. Bolyard.</p> <p>17 BY MS. GEIST:</p> <p>18 Q. Did -- other than your communications with 19 counsel in this litigation, did you speak with anyone 20 else with respect to your opinions about Mrs. Alonso, 21 Mrs. Wheeler, and Mrs. Bolyard?</p> <p>22 A. No.</p> <p>23 Q. Did you talk to any other medical doctors or 24 experts for plaintiffs in the litigation about your 25 opinions?</p>
<p style="text-align: right;">Page 506</p> <p>1 A. Well, those notes are all converted into 2 electronic digital form.</p> <p>3 Q. So did you get rid of the written notes?</p> <p>4 A. So the written notes are gone, yes.</p> <p>5 Q. Same -- same method for Mrs. Wheeler and 6 Mrs. Bolyard? Did you take written notes and then now 7 they're gone?</p> <p>8 MS. GAYLE: Object to form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Yeah. I can't speak to all of them. I mean, 11 again, there is, you know, 11,000 -- 1100 pages. I told 12 you 1900 for Alonso. I can't say what I did with each 13 one. I didn't keep that kind of a record of what I did 14 as far as records go, I mean, handwritten notes or not.</p> <p>15 I put Post-It notes on things to come back to it, but I 16 don't save Post-It notes.</p> <p>17 Q. Those Post-It notes are not available to us 18 now either, are they?</p> <p>19 A. No. They're not available to me either. I 20 don't have them.</p> <p>21 Q. Did you create separate Word documents or some 22 other electronic memorialization when you went through 23 the medical records for Mrs. Alonso, Mrs. Wheeler, and 24 Mrs. Bolyard?</p> <p>25 MS. GAYLE: Object to form.</p>	<p style="text-align: right;">Page 508</p> <p>1 A. No.</p> <p>2 Q. Dr. Elliott, if you look with me at your 3 report for Mrs. Alonso --</p> <p>4 A. Yes.</p> <p>5 Q. -- do you have that in front of you?</p> <p>6 A. Yes, I do.</p> <p>7 Q. Is that your -- is that your own copy?</p> <p>8 A. This is my own highlighted copy, yes. With no 9 notes on it, but it is highlighted.</p> <p>10 Q. Well, that was my next question. Do you have 11 any handwritten notes on that copy?</p> <p>12 A. Yeah. The only thing is, as I was going 13 through it -- yeah. I have one note indicating, on page 14 6, there is an accidental duplication. I duplicated 15 what was said twice. I just noticed that.</p> <p>16 Q. Okay.</p> <p>17 A. So other --</p> <p>18 Q. From page 6 to 7, and I noticed that as 19 well --</p> <p>20 A. Yeah.</p> <p>21 Q. -- it's a pure duplication?</p> <p>22 A. That is -- that is correct. Otherwise, they 23 are highlighted, dates are circled so I can find them 24 easier. That appears to be it. And I think -- and then 25 I noticed a typographical error on page 11. I put -- I</p>

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<p style="text-align: right;">Page 509</p> <p>1 accidentally put the Cook device down on the last 2 paragraph instead of the Bard device. That's a 3 typographical error.</p> <p>4 Q. Did you notice any other errors or 5 inaccuracies in your report that we need to change here 6 today?</p> <p>7 A. Let me go through it page by page to make 8 sure.</p> <p>9 Q. Sure.</p> <p>10 A. Not that I see on this.</p> <p>11 Q. Doctor, you can feel free to review and refer 12 to that version of your report as I ask you questions 13 about it. But I'm just going to mark it as an exhibit 14 to your deposition if that's okay with you.</p> <p>15 A. Sure. That is perfectly fine.</p> <p>16 Q. Thank you. Now, we can toss documents at one 17 another.</p> <p>18 (Elliott Deposition Exhibit No. 30 19 was marked for identification.)</p> <p>20 BY MS. GEIST:</p> <p>21 Q. And that will be, for the record, Exhibit 30, 22 which is Dr. Elliott's copy of his report for 23 Mrs. Alonso with some highlighting and handwritten 24 notes.</p> <p>25 MS. GAYLE: And, Counsel, I haven't seen that</p>	<p style="text-align: right;">Page 511</p> <p>1 MS. GEIST: For the record, we just took a break 2 and counsel and I both agreed that Exhibit 30 appears to 3 be a draft of Dr. Elliott's report and was not the 4 doctor's version of the final report. So, for the 5 record, Exhibit 30 is being withdrawn and not being put 6 into evidence.</p> <p>7 MS. GAYLE: Thank you, Counsel.</p> <p>8 MS. GEIST: Thank you.</p> <p>9 BY MS. GEIST:</p> <p>10 Q. Doctor, you have what we've marked as Exhibit 11 29, which is your final report, correct?</p> <p>12 A. That is correct.</p> <p>13 Q. And you've added some highlights to that 14 report for efficiency purposes and to help us move along 15 quickly with respect to dates and other information?</p> <p>16 A. Correct.</p> <p>17 Q. Okay. I had started to ask you about the 18 error, the typo you noted on page 11?</p> <p>19 A. Yes.</p> <p>20 Q. And you said that's the Cook device and SIS 21 sling?</p> <p>22 A. SIS mesh sling, that's correct.</p> <p>23 Q. Are you -- are you involved in litigation on 24 behalf of the plaintiffs against that company?</p> <p>25 A. Yes, I am.</p>
<p style="text-align: right;">Page 510</p> <p>1 myself, so...</p> <p>2 MS. GEIST: You didn't? Now, let me just show it 3 to you, and I'm going to look through it quickly.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. You said, Doctor, that, on the last page of 6 your report, you had a typo on page 11. And that 7 sentence reads, Mrs. Alonso was unable to make a fully 8 informed decision about having the Cook device 9 implanted?</p> <p>10 A. Correct.</p> <p>11 Q. And you said that should read the Bard device?</p> <p>12 A. Correct.</p> <p>13 Q. What's the Cook device?</p> <p>14 A. Cook device is an SIS sling made of collagen, 15 porcine collagen.</p> <p>16 Q. And who manufactures that product?</p> <p>17 A. Cook.</p> <p>18 MS. GAYLE: Counsel, could we go off record just 19 for a second?</p> <p>20 MS. GEIST: Sure.</p> <p>21 VIDEO TECHNICIAN: We're off the record. The time 22 is 9:33 a.m.</p> <p>23 (A recess was had.)</p> <p>24 VIDEO TECHNICIAN: We're back on the record. The 25 time is 9:42 a.m.</p>	<p style="text-align: right;">Page 512</p> <p>1 Q. And have you provided any expert reports in 2 that litigation?</p> <p>3 A. Yeah. Yes.</p> <p>4 Q. Have you provided any deposition testimony in 5 that litigation?</p> <p>6 A. No.</p> <p>7 Q. Are you scheduled for deposition in that 8 litigation?</p> <p>9 A. Yes.</p> <p>10 Q. When is that going to take place?</p> <p>11 A. January 3rd.</p> <p>12 Q. January 3rd of 2015?</p> <p>13 A. Correct.</p> <p>14 Q. In this case, Doctor, Mrs. Alonso was also 15 implanted with the Align sling, correct?</p> <p>16 A. That is correct.</p> <p>17 Q. Okay.</p> <p>18 A. She had two surgeries at the same time.</p> <p>19 Q. And I understand, from your report and your 20 testimony yesterday, that you are not offering any 21 opinions with respect to the Bard Align sling; is that 22 correct?</p> <p>23 A. Well, unless I'm asked. I'm not here to talk 24 about the Align sling. This individual had the product 25 implanted. If you ask me about it, I will answer.</p>

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<p style="text-align: right;">Page 513</p> <p>1 Q. In your report, you're not providing any 2 opinions with respect to the Bard Align sling, correct? 3 MS. GAYLE: Objection. Form. 4 BY MS. GEIST: 5 Q. Is there any -- well, let me fix it. 6 Is there any opinion in your report for 7 Mrs. Alonso with respect to the Bard Align sling 8 product?</p> <p>9 A. Not specifically. The problem comes that 10 she's had two products that are placed in the same 11 region. They're made out of the same type of mesh. And 12 so there's going to be complications overlying that. I 13 am here for the Avaulta product. But she has two 14 products that were placed in her.</p> <p>15 Q. Understood. But you haven't reached any 16 opinions, to a reasonable degree of medical certainty, 17 that Mrs. Alonso's Bard Align sling caused her any 18 complications; is that correct?</p> <p>19 MS. GAYLE: Object to form. Mischaracterizes 20 testimony. 21 BY THE WITNESS: 22 A. Well, no, that wouldn't necessarily be 23 correct, again, because we have a polypropylene mesh, 24 heavyweight that's put into the obturator foramen, this 25 exact same location as the Avaulta arms. And so that</p>	<p style="text-align: right;">Page 515</p> <p>1 problems. However, the Align sling could be a 2 contributing factor to it. Because if the Avaulta mesh 3 gets infected, the Avaulta POP mesh gets infected, she 4 also has the other mesh there which is going to get 5 infected. So it becomes complicated.</p> <p>6 My opinion, as I outline in here, that the 7 inciting event, the culprit which causes the problems, 8 was the Avaulta mesh.</p> <p>9 BY MS. GEIST: 10 Q. And not the Align sling? 11 MS. GAYLE: Object to form. 12 BY MS. GEIST: 13 Q. Is that correct? 14 A. Based upon statistics and my experience and 15 review of the literature, more likely than not it is the 16 Avaulta mesh that caused the problem and not the Align 17 sling.</p> <p>18 Q. Thank you. Okay. So, Doctor, what I've tried 19 to do is summarize, as best I can, from looking at your 20 report, your opinions with respect to Mrs. Alonso. 21 Okay. So if you look at beginning on page 5 of your 22 report and then continuing on to page 6 -- 23 A. Yes. 24 Q. And just let me know, is this a fair summary 25 of your opinions, that Mrs. Alonso has experienced</p>
<p style="text-align: right;">Page 514</p> <p>1 makes it quite complicated. I have two large pieces of 2 mesh going to the same region. So I -- I can't state 3 that. I can state what I've stated in my report.</p> <p>4 Q. Well, in your report, unless I'm missing it 5 somewhere, you attribute the complications and problems 6 that Mrs. Alonso describes to the Avaulta product, true? 7 A. It is my opinion of going through the -- all 8 that's happened with her, look at the differential 9 diagnosis, looking at the literature out there, 10 statistics and my experience, that, in her situation, it 11 was the Avaulta mesh -- excuse me, the Avaulta POP mesh 12 which is creating her problem.</p> <p>13 Q. Okay. So that's just what I want to 14 understand. 15 A. Yeah. 16 Q. You're not going to give an opinion, in 17 Mrs. Alonso's case, that it was the Bard Align sling 18 that has caused her any problems or complications; is 19 that true? 20 MS. GAYLE: Object to form. 21 BY THE WITNESS: 22 A. No. I'm going off -- again, this is playing 23 the game of statistics of volume of mesh, what is more 24 likely. And more likely than not with medical 25 certainty, it is the Avaulta POP that caused her</p>	<p style="text-align: right;">Page 516</p> <p>1 pelvic pain, dyspareunia, urge incontinence, as well as 2 some long-term potential impacts due to the loss of 3 physical intimacy and that all of these problems and 4 complications are caused by the Bard Avaulta product? 5 MS. GAYLE: Object to form. 6 BY MS. GEIST: 7 Q. Is that a fair summary? 8 MS. GAYLE: Object to form. 9 BY THE WITNESS: 10 A. Yeah. Based upon my experience, my review of 11 the literature, attendance and giving lectures on the 12 international and national stage and review and the exam 13 of this patient and review of the records, as outlined 14 in my notes here, that is correct. 15 Q. Okay. So, at least the problems -- and I'm 16 trying to summarize so we can streamline a little bit. 17 The problems that we're talking about with respect to 18 Mrs. Alonso or the complications that you say are 19 attributed to the Bard Avaulta product are pelvic pain, 20 dyspareunia, urge incontinence, and then long-term 21 impact of lack of physical intimacy; is that correct? 22 MS. GAYLE: Object to form. 23 BY MS. GEIST: 24 Q. And then, Doctor, just so we're clear, on 25 pages 5 to 6, I'm looking at what you have numbered 1,</p>

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<p>1 2, 3, and 4?</p> <p>2 A. Yeah. Correct. No. I think that is, as I've 3 outlined here, I think that's a fair assessment.</p> <p>4 Q. Okay. And you -- tell me how you went about 5 concluding that these four complications or problems 6 that Mrs. Alonso alleges she's experiencing were caused 7 by the Bard Avaulta product?</p> <p>8 A. That's a fairly drawn-out process entailing, 9 you know, 21 years of medical experience, review of the 10 literature, examination of patients -- not just this 11 one, but in my career -- then review of her medical 12 records, review of all of the potential -- the 13 differential diagnosis of other factors that could be 14 contributing to it or not, and then putting them all 15 together, all factors, and coming up with this 16 diagnosis.</p> <p>17 Q. So did you do a differential diagnosis?</p> <p>18 A. Yes.</p> <p>19 Q. Did you rule in any other medical problems or 20 conditions that may have caused the complaints that 21 Mrs. Alonso has and then rule them out?</p> <p>22 A. Well, I approach each individual. Again, this 23 is because I work at a tertiary care center where we 24 have to keep an open mind of each individual coming in. 25 I do not disregard the outside doctor's opinions, but I</p>	<p>Page 517</p> <p>1 reaching your differential diagnosis for Mrs. Alonso?</p> <p>2 A. Well, the list of potential differential 3 diagnoses in a female in this age group of pelvic 4 issues, you know, is probably a hundred different 5 things; MS, Parkinson's, myositis, endometriosis. Did I 6 go through, as you say, and list out all of those? I 7 did not. But those would go through -- that goes 8 through my thought process, and I do that on every 9 single patient that I do every single day in my work.</p> <p>10 Q. Okay. So just so I'm clear, there's 11 nowhere -- if we look at your report, there is nowhere 12 in your report that lists the other medical conditions 13 or problems that you considered specifically for 14 Mrs. Alonso and then ruled them out or concluded that 15 they were not causing her pelvic pain, dyspareunia, urge 16 incontinence?</p> <p>17 MS. GAYLE: Object to form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I do not go through and list out the rare 20 issues of multiple sclerosis and endometriosis, 21 interstitial cystitis. I look at -- I think about those 22 things. I then look at the medical records to see if 23 there is any support for them. If I find support for 24 that possibility, then I will include that in there. 25 But I'm not going to list every possible thing.</p>
<p>Page 518</p> <p>1 always try and look at it with a critical eye. Do I 2 agree or not?</p> <p>3 So as I went through the list and looked at 4 her very carefully, looked at potential etiologies of 5 neurologic disorders, preexisting neurologic disorders, 6 which I'm not aware of any, any preexisting uterine or 7 GYN chronic pain syndromes, endometriosis, pelvic floor 8 myalgia, fibromyalgia, myositis, multiple sclerosis. 9 The list is -- sounds infinite, but we have to, again, 10 figure out all of the things that could be playing a 11 role and then looking at her and her data, her medical 12 records and her exam. And so I might not list all of my 13 differential diagnoses, but those are all of the things 14 that go through my thought process.</p> <p>15 Q. Okay. So would you agree with me that, when 16 we look at your report for Mrs. Alonso, it doesn't tell 17 us what you considered and ruled out in reaching your 18 differential diagnosis?</p> <p>19 MS. GAYLE: Object to form. The report, he's 20 already testified, contains his opinions. It's an 21 unfair characterization of the evidence.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. Well, does the report in any place, and you 24 can point me to it, Dr. Elliott, if I'm missing it, does 25 the report tell us what you ruled in or considered in</p>	<p>Page 520</p> <p>1 Brain trauma, that can -- that can lead to it. 2 Spinal cord injury can lead to it. I do not put that in 3 there. But then, when I do my exam and I state 4 neurologically normal, then that, to me, my statement 5 neurologically normal, that rules out MS, Parkinson's, 6 spinal cord injury.</p> <p>7 Q. Understood, Doctor. And I'm not trying to be 8 tricky about this. I just want to see if you agree with 9 me that, if we look at your report, there is no place in 10 the report that provides us with a list of what medical 11 conditions or problems that you considered with respect 12 to Mrs. Alonso when reaching your differential 13 diagnosis. If there is some -- if it's in the report 14 someplace and you can point it out to me, I would 15 appreciate it.</p> <p>16 MS. GAYLE: Objection. Asked and answered.</p> <p>17 BY THE WITNESS:</p> <p>18 A. The physical -- yeah, I mean, I've gone over 19 this several times now. The differential diagnosis that 20 I go through when I encounter a patient, initially, that 21 differential diagnosis, as I'm trained, should be 22 infinite. And then you very rapidly, through 23 experience, review of the medical literature, you can 24 narrow that differential diagnosis down rapidly. But do 25 I go through and list every possible thing? Again, MS,</p>

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<p style="text-align: right;">Page 521</p> <p>1 let's talk about that. To me, also, when I say 2 neurologic exam without gross deficit, that's going to 3 be excluding all of those things, and the same thing 4 with the abdominal exam, everything. So I don't go out 5 and list every possibility.</p> <p>6 Q. Is there a list in the report or a note about 7 anything, any medical condition you considered with 8 respect to Mrs. Alonso and you ruled it out, in 9 concluding that the Bard Avaulta mesh was the cause of 10 her injuries and problems she's complaining about?</p> <p>11 MS. GAYLE: Objection. Asked and answered.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Yeah. I think we're -- I mean, each time we 14 ask this, it's going to be the exact same answer. I do 15 not go through and list out every possibility of 16 differential diagnosis. Again, that list is infinite.</p> <p>17 But in my experience and training, as I'm 18 going through the medical records, we're knocking each 19 one of those out. But I don't go through and write 20 those all out for you in a list. Again, that list is 21 too long.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. Okay. So there is no list. You can agree 24 with me on that, there is no list here in the report?</p> <p>25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 523</p> <p>1 all I'm asking for you is to answer my question, is 2 there a list in your report, yes or no? Can you answer 3 that question for me?</p> <p>4 MS. GAYLE: Objection, counsel, argumentative.</p> <p>5 BY MS. GEIST:</p> <p>6 Q. Can you answer that question, Dr. Elliott?</p> <p>7 MS. GAYLE: And object to form and asked and 8 answered.</p> <p>9 BY THE WITNESS:</p> <p>10 A. As I've said, when the judge asks me directly, 11 I can always answer him and I'll answer him in the exact 12 same way. A differential diagnosis is infinite to start 13 off with. To --</p> <p>14 Q. Why won't you tell me that there is no list in 15 your report?</p> <p>16 A. Okay.</p> <p>17 Q. Why don't you just tell me there is no list in 18 your report, and then we can move on to the next 19 question?</p> <p>20 A. Well, you can --</p> <p>21 MS. GAYLE: Objection. Argumentative. Motion to 22 strike counsel's preface to the question.</p> <p>23 BY THE WITNESS:</p> <p>24 A. You can -- you can read what is in the report. 25 But I, as an expert, cannot include every possible</p>
<p style="text-align: right;">Page 522</p> <p>1 BY THE WITNESS:</p> <p>2 A. As I've stated several times now, I go through 3 all of those lists of differential diagnoses in my head. 4 That includes every possible thing that can lead to 5 pelvic pain. I am a member of the International Pelvic 6 Pain Society. This is what I do for a living. But I'm 7 not going to go through and list out every possible 8 diagnosis that could lead to it that I have considered. 9 Because then you're talking about going back 25 years of 10 medical education, neurologic issues, pelvic floor, GYN, 11 endometriosis. So I considered those. I did not go out 12 and spell out each one of those separately, though.</p> <p>13 Q. Okay. So the list is in your head, not in the 14 report?</p> <p>15 MS. GAYLE: Object to form.</p> <p>16 BY MS. GEIST:</p> <p>17 Q. Is that correct?</p> <p>18 MS. GAYLE: Mischaracterizes testimony.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I've stated that over and over, and I'm going 21 to state the same thing again.</p> <p>22 Q. I know. But, Doctor, here is my point, okay, 23 at the trial in this case, if Mrs. Alonso's case goes to 24 trial, the judge will ask you to say yes or no, is there 25 a list in your report. And all I'm asking you is to --</p>	<p style="text-align: right;">Page 524</p> <p>1 diagnosis that I consider. I considered endometriosis. 2 I found no support for it. I considered interstitial 3 cystitis. I found no support for it. MS, neurologic, 4 spinal cord injuries, cervical injuries, lumbar injury, 5 lumbar disc disease, I considered all of those. I do 6 not then go and put down all of those in a form that you 7 want.</p> <p>8 Q. Now, you won't answer my question, but let me 9 ask you this. You said a number of times you can't 10 possibly put down and list every possible alternative 11 cause for the problems Mrs. Alonso is complaining of. 12 Did you put in your report even one possible alternative 13 cause for the problems Mrs. Alonso is complaining of?</p> <p>14 MS. GAYLE: Object to form.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. That you considered and ruled out --</p> <p>17 MS. GAYLE: Object.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. -- in reaching your opinions? Did you include 20 even one medical condition or problem?</p> <p>21 MS. GAYLE: Object to form. Asked and answered.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Okay. In my opinion, I considered all 24 potential differential diagnoses. The report states 25 what the report states. I did not go through and list</p>

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<p style="text-align: right;">Page 525</p> <p>1 out all that I had considered.</p> <p>2 Q. You didn't even list one though, correct?</p> <p>3 MS. GAYLE: Objection. Asked and answered, and</p> <p>4 mischaracterizes his testimony.</p> <p>5 BY THE WITNESS:</p> <p>6 A. I considered all based upon my experience at a</p> <p>7 tertiary medical center, a member of the International</p> <p>8 Pelvic Pain Society, who deals with meshes, pain, et</p> <p>9 cetera, on a daily basis. I considered all. I did not</p> <p>10 go through and list out all of the possible</p> <p>11 contributions that went through my head in coming up</p> <p>12 with a diagnoses.</p> <p>13 Q. All right. In the interest of time, Doctor,</p> <p>14 I'm going to move on. But can you tell me specifically</p> <p>15 for Mrs. Alonso what specific medical conditions or</p> <p>16 problems did you consider for her as a specific</p> <p>17 plaintiff in reaching your differential diagnosis?</p> <p>18 A. I considered -- again, the list is large. I</p> <p>19 considered dealing with central nervous system</p> <p>20 conditions, Parkinson's, MS, brain trauma, radiation to</p> <p>21 the brain, spinal cord injuries, cervical, thoracic,</p> <p>22 lumbar, lumbar disc disease, endometriosis, interstitial</p> <p>23 cystitis, ovarian etiologies, ovarian remnant, pelvic</p> <p>24 congestion syndrome, primary bladder dysfunction,</p> <p>25 neurologic injury, local diabetes, myositis.</p>	<p style="text-align: right;">Page 527</p> <p>1 diagnoses due to the inflammation of the product within</p> <p>2 her body. I found no evidence of a central nervous</p> <p>3 system defect in her.</p> <p>4 Q. In reaching your differential diagnosis for</p> <p>5 Mrs. Alonso, did you consider her history with heavy</p> <p>6 bleeding and clots as a possible alternative cause for</p> <p>7 some of the pain and discomfort she's complaining about?</p> <p>8 A. Yes and no to that. Yes. She had heavy</p> <p>9 periods, abnormalities of uterine issues. However, that</p> <p>10 was prior to her surgery. Following her surgery and no</p> <p>11 longer having a uterus, those issues are excluded.</p> <p>12 Q. Did you consider, in reaching your</p> <p>13 differential diagnosis, the fact that Mrs. Alonso had</p> <p>14 been diagnosed with diverticulitis?</p> <p>15 A. Yes. Diverticulitis, colon issues, are</p> <p>16 considered in a differential diagnosis. However, in</p> <p>17 dealing with being an expert in pelvic pain and a member</p> <p>18 of the International Pelvic Pain Society, pelvic pain</p> <p>19 due to diverticulitis, diverticulosis, or a perforated</p> <p>20 diverticulum is different than this type of pain.</p> <p>21 Q. Diverticulitis, the primary presentation of</p> <p>22 that medical condition is pelvic pain, true?</p> <p>23 A. It possibly can be pelvic pain if it ruptures.</p> <p>24 It is also associated with fever, chills, systemic</p> <p>25 defects, and usually located on the left-hand side where</p>
<p style="text-align: right;">Page 526</p> <p>1 Q. Did you see anything, when you reviewed</p> <p>2 Mrs. Alonso's medical records, anything specific in</p> <p>3 Mrs. Alonso's history that you considered and ruled out</p> <p>4 as a potential cause of her problems in reaching your</p> <p>5 differential diagnosis?</p> <p>6 MS. GAYLE: Objection, form. And objection, asked</p> <p>7 and answered.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yeah. I mean, as far as when I reviewed her</p> <p>10 medical records, I guess I'm confused on your question.</p> <p>11 Q. Yeah. Well, you just gave me a long list of</p> <p>12 things that may or may not apply to Mrs. Alonso. Did</p> <p>13 you -- did you -- when you reviewed her medical history</p> <p>14 and her medical records, was there anything that you</p> <p>15 considered about Mrs. Alonso's history that you ruled</p> <p>16 out in reaching your differential diagnosis that the</p> <p>17 Bard Avaulta product was the cause of her problems?</p> <p>18 MS. GAYLE: Objection.</p> <p>19 THE WITNESS: I --</p> <p>20 MS. GAYLE: Asked and answered.</p> <p>21 BY THE WITNESS:</p> <p>22 A. I ruled out that list I just went off of,</p> <p>23 however many those were. I ruled those out as the</p> <p>24 primary cause of her problem. Issues like myositis,</p> <p>25 inflammation of the muscle, could be one of the</p>	<p style="text-align: right;">Page 528</p> <p>1 the sigmoid is located.</p> <p>2 Q. So did you consider diverticulitis --</p> <p>3 diverticulitis as a possible cause for some of the</p> <p>4 pelvic pain problems Mrs. Alonso is complaining of?</p> <p>5 MS. GAYLE: Objection. Asked and answered.</p> <p>6 BY THE WITNESS:</p> <p>7 A. As I mentioned, absolutely, but then I</p> <p>8 analyzed and I have a fairly extensive -- because I'm a</p> <p>9 reconstructive surgeon and a member of the International</p> <p>10 Pelvic Pain Society, diverticulitis, she had no evidence</p> <p>11 of active diverticulitis. Diverticulosis is not</p> <p>12 commonly associated with pain. It's also a different</p> <p>13 type of pain. She had no fever, no chills, no evidence</p> <p>14 of an intraabdominal pelvic abscess.</p> <p>15 Q. How about internal hemorrhoids? Did</p> <p>16 Mrs. Alonso have internal hemorrhoids?</p> <p>17 A. I don't recall.</p> <p>18 Q. Did you consider internal hemorrhoids as a</p> <p>19 possible alternative cause for pelvic pain?</p> <p>20 A. Internal hemorrhoids are usually painless.</p> <p>21 They may bleed per rectum with bright red blood. They</p> <p>22 will not cause vaginal pain. So, in my experience, that</p> <p>23 is theoretically a source of bleeding, but it is not a</p> <p>24 source of vaginal pain or vaginal abscess following a</p> <p>25 surgery.</p>

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<p style="text-align: right;">Page 529</p> <p>1 Q. One of the things you mentioned with respect 2 to Mrs. Alonso is urge incontinence?</p> <p>3 A. Correct.</p> <p>4 Q. Do you -- is it your opinion that the Bard 5 Avaulta product caused her to experience urge 6 incontinence?</p> <p>7 A. With, again, a review of the literature and 8 based upon my experience and where the Avaulta mesh is 9 placed in the vesicovaginal space and reviewing the 10 surgeon's records, which is consistent where he placed 11 it -- those are where the nerves for bladder function 12 occur -- if a mesh becomes infected or inflamed or 13 contracts, it will affect those nerves. So, yes, that 14 could be a source of her overreactive bladder.</p> <p>15 Q. Did you consider the fact that she was 16 diagnosed with overreactive bladder or urge 17 incontinence -- those are the same things, right, 18 Doctor? Don't we -- don't medical doctors use those 19 terms interchangeably? Urge incontinence means 20 overreactive bladder syndrome?</p> <p>21 MS. GAYLE: Object to form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Overreactive bladder is the entire 24 constellation of symptoms of urgency, frequency, urge 25 incontinence, where urge incontinence is a more specific</p>	<p style="text-align: right;">Page 531</p> <p>1 syndrome at the end of 2013?</p> <p>2 MS. GAYLE: Objection.</p> <p>3 BY MS. GEIST:</p> <p>4 Q. If she had said that, does that mean that the 5 Bard products could not have been increasing the 6 severity of the overreactive bladder syndrome?</p> <p>7 MS. GAYLE: Objection. Objection. Form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Absolutely not. Because, remember, the 10 vesicovaginal plexus, which are the nerves that control 11 bladder function, are located in the vesicovaginal plane 12 where the Avaulta mesh goes. So, if you have a mesh 13 that contracts, degrades, causes inflammation and traps 14 nerves, that can lead to progression of the disease just 15 like we see progression and increase of mesh extrusion.</p> <p>16 Q. Are you aware that Mrs. Alonso has a history 17 of extensive lumbar disc disease, joint swelling?</p> <p>18 A. Correct.</p> <p>19 Q. Back problems?</p> <p>20 A. Correct.</p> <p>21 Q. You're aware of all of that?</p> <p>22 A. Well, I would have to go back and look at the 23 records at exactly where all of the lumbar disc disease 24 is. But lumbar disc disease is in my differential 25 diagnosis, as I mentioned earlier, of neurologic</p>
<p style="text-align: right;">Page 530</p> <p>1 subset within that.</p> <p>2 Q. Did you consider the fact that she was 3 diagnosed with an overreactive bladder and was on 4 Vesicare prior to the implant of the Bard product?</p> <p>5 A. Absolutely. And so my previous answer was 6 that the Avaulta, where it's located, is going to be 7 contributing to possibly worsening of that condition.</p> <p>8 Q. Can you say, with a reasonable degree of 9 medical certainty, that the Bard product changed, in any 10 way, the condition she already had prior to the implant?</p> <p>11 A. I would have to look at, and I'd have to go 12 back and look at her records here, the chronologic -- 13 the chronology of the situation, the severity of her 14 overreactive bladder prior to and after and then 15 currently.</p> <p>16 If the disease process has dramatically 17 increased following the implantation of it, the Avaulta 18 may not be the primary cause if she had a preexisting 19 condition, but it can worsen it. The same thing if an 20 individual has pelvic pain prior to surgery, but it 21 increases dramatically. The Avaulta may not have caused 22 the underlying problem, but then it worsens the 23 condition.</p> <p>24 Q. Did you consider the fact that Mrs. Alonso had 25 said she had no complaints of overreactive bladder</p>	<p style="text-align: right;">Page 532</p> <p>1 abnormalities.</p> <p>2 Q. Did you consider those conditions as possibly 3 contributing to Mrs. Alonso's complaints of pain?</p> <p>4 MS. GAYLE: Object.</p> <p>5 BY MS. GEIST:</p> <p>6 Q. And lack of physical intimacy?</p> <p>7 MS. GAYLE: Objection. Asked and answered 8 previously.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Yes. Based upon my education and the fact 11 that I did a fellowship in what's called neurourology 12 and a member of the International Pelvic Pain Society, 13 I'm very well aware and one of the leaders in the field 14 as far as the understanding of neuroanatomy and its 15 effects upon the pelvis.</p> <p>16 Lumbar disc disease can, no question, cause 17 pain. But leading to isolated pelvic pain where there 18 is a firm nodule in the vagina, lumbar disc disease does 19 not cause that. If you isolate it to causing foot pain, 20 leg pain, sciatic-type pain, then Avaulta does not cause 21 that. Disc disease causes that.</p> <p>22 Q. Does Mrs. Alonso have a handicapped sticker on 23 her car?</p> <p>24 MS. GAYLE: Objection.</p> <p>25 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 533</p> <p>1 A. I have no knowledge.</p> <p>2 Q. You have no -- I thought you said you read her</p> <p>3 deposition?</p> <p>4 MS. GAYLE: Objection, Counsel. Mischaracterizes</p> <p>5 his testimony.</p> <p>6 BY MS. GEIST:</p> <p>7 Q. Did you read her deposition?</p> <p>8 A. Yes. I read her deposition. I do not</p> <p>9 remember every word of her deposition, and I read many</p> <p>10 people's depositions of hundreds and hundreds of pages.</p> <p>11 I cannot recall every single word of it.</p> <p>12 Q. Did you -- so you have no idea why she has</p> <p>13 that handicapped sticker on her car --</p> <p>14 MS. GAYLE: Objection.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. -- what medical condition caused her to get</p> <p>17 that handicapped sticker?</p> <p>18 MS. GAYLE: Objection, Counsel.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I've already answered the question. If I</p> <p>21 didn't know she had a handicapped sticker, I don't know</p> <p>22 why she would have a handicapped sticker.</p> <p>23 Q. Did you read in her deposition how she</p> <p>24 testified that it's hard for her to walk and she has</p> <p>25 pain when she walks and that's the reason why she has</p>	<p style="text-align: right;">Page 535</p> <p>1 know what was in the deposition. I've asked to see this</p> <p>2 deposition, to look at that in its entirety. Not that I</p> <p>3 don't doubt you, but I would like to see the whole</p> <p>4 comment.</p> <p>5 Q. So you don't know the medical condition that</p> <p>6 caused her to go and get the sticker?</p> <p>7 MS. GAYLE: Objection.</p> <p>8 BY MS. GEIST:</p> <p>9 Q. Is that -- is that true?</p> <p>10 MS. GAYLE: Objection to form. Objection, asked</p> <p>11 and answered. Objection, mischaracterizes Mrs. Alonso's</p> <p>12 testimony.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I think the best thing, let's take a look at</p> <p>15 that deposition and what she states. I would like to</p> <p>16 see, in the entirety, those comments.</p> <p>17 Q. So the answer to my question is, you don't</p> <p>18 know the medical condition for which she got a</p> <p>19 handicapped sticker on her car?</p> <p>20 MS. GAYLE: Objection.</p> <p>21 BY MS. GEIST:</p> <p>22 Q. And which causes her pain with walking?</p> <p>23 MS. GAYLE: Objection.</p> <p>24 BY MS. GEIST:</p> <p>25 Q. Is that true, Doctor?</p>
<p style="text-align: right;">Page 534</p> <p>1 the handicapped sticker due to a specific medical</p> <p>2 condition?</p> <p>3 MS. GAYLE: Object to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. Okay. I would like -- the important thing,</p> <p>6 probably, let's pull out that deposition and read that</p> <p>7 exactly because I would like to know what type of pain</p> <p>8 she is describing. In my interaction with her, as I've</p> <p>9 talked about it here, neurologic issues related to</p> <p>10 lumbar disc disease can cause pain in the legs, can</p> <p>11 cause difficulty ambulating. No question it can do it.</p> <p>12 But when I'm also then correlating that with</p> <p>13 my exam and my interaction with her as far as what pain</p> <p>14 happens when standing, sitting, lying down and then the</p> <p>15 physical exam. As I mentioned, lumbar disc disease will</p> <p>16 not cause pinpoint tenderness in the obturator foramen</p> <p>17 and will not cause scarring in the vagina.</p> <p>18 Q. Sitting here today, do you know why, what</p> <p>19 specific medical condition Mrs. Alonso has that caused</p> <p>20 her to go and get a handicapped sticker for her car?</p> <p>21 MS. GAYLE: Object to form. Asked and answered.</p> <p>22 BY THE WITNESS:</p> <p>23 A. I've already stated I did not know she had a</p> <p>24 handicapped sticker. The fact that she does tells me</p> <p>25 that she's got some impairment. I do not -- I don't</p>	<p style="text-align: right;">Page 536</p> <p>1 MS. GAYLE: Objection. Asked and answered.</p> <p>2 BY THE WITNESS:</p> <p>3 A. You are asking me to trust what you are</p> <p>4 stating. And I would like to see that document and</p> <p>5 let's look through it. I will be more than happy to</p> <p>6 render an opinion based upon that deposition.</p> <p>7 Q. Did -- after a woman has a pelvic floor</p> <p>8 surgery like the type Mrs. Alonso had, the implant of a</p> <p>9 transvaginal mesh product to repair a pelvic organ</p> <p>10 prolapse, after a woman has such a procedure, are they</p> <p>11 normally instructed by a physician to not engage in</p> <p>12 sexual intercourse for a specific period of time?</p> <p>13 A. I can't speak to what happens in every</p> <p>14 practice. I know what my instructions are.</p> <p>15 Q. What are your -- what are you instructions?</p> <p>16 A. No sexual activity for six weeks.</p> <p>17 Q. Why?</p> <p>18 A. For concerns about breaking down the incision.</p> <p>19 Q. So if a woman engages in sexual intercourse</p> <p>20 during that six-week healing process, what could happen</p> <p>21 to the incision?</p> <p>22 A. Well, since I don't use any meshes, it will</p> <p>23 just probably delay healing a bit because the incision</p> <p>24 could break down. It's much more of an important issue</p> <p>25 when meshes are in place.</p>

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<p style="text-align: right;">Page 537</p> <p>1 Q. Is that because it could actually cause some 2 sort of mesh exposure and open the -- open the incision, 3 in other words?</p> <p>4 A. Possible --</p> <p>5 MS. GAYLE: Object to form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Possibly. I am unaware of any. I would have 8 to look at the IFU, what Bard warns as far as how long 9 to avoid sexual activity.</p> <p>10 Q. Would you agree with me, if a woman engages in 11 sexual activity before being cleared by her doctor, that 12 that would not be a good thing and could possibly cause 13 complications?</p> <p>14 A. I disagree with that.</p> <p>15 Q. I thought you just told me that, if a woman 16 engages in sexual intercourse during the healing 17 process, that could cause some complications with 18 respect to healing and the suture?</p> <p>19 A. That -- I answered that. That's correct.</p> <p>20 Q. Okay.</p> <p>21 A. But your other question was different.</p> <p>22 Q. Did you consider, in reaching your opinions 23 with respect to Mrs. Alonso and the complications she 24 had that you say resulted from the Bard Avaulta product, 25 did you consider the fact that she may have engaged in</p>	<p style="text-align: right;">Page 539</p> <p>1 records to see when she regained. There is going to be 2 a lot of qualifiers. Did she resume sexual activity two 3 days postop or four weeks, six weeks, eight weeks?</p> <p>4 Q. Do you know, from your review of the records 5 in Mrs. Alonso's case, when she began resuming sexual 6 activity and whether she, in fact, adhered to her 7 doctor's instructions; do you know that?</p> <p>8 MS. GAYLE: Object to form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I would want to see the records. I don't 11 recall.</p> <p>12 Q. You do not recall sitting here today?</p> <p>13 A. I do not recall the specifics of that. That's 14 why I'd want to see the records, to refresh my memory.</p> <p>15 Q. Doctor, you talk in your report about the lack 16 of physical intimacy has already cost Mrs. Alonso a 17 major component to her quality of life. And then you 18 state long-term impact on her quality of life is 19 difficult to accurately ascertain, however many studies 20 have shown long-term negative impact leads to feelings 21 of isolation, loneliness, depression, and suicide. Did 22 I read that correctly?</p> <p>23 A. Correct.</p> <p>24 Q. And that is actually an identical opinion that 25 you provided in Mrs. Wheeler's and Mrs. Bolyard's case,</p>
<p style="text-align: right;">Page 538</p> <p>1 sexual intercourse prior to being cleared by her doctor?</p> <p>2 MS. GAYLE: Objection to form. Objection, 3 mischaracterizes the testimony of the parties.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I don't know what she was instructed. We 6 would have to go look back at the medical records of 7 what she was instructed. Clearance by a medical doctor 8 does not necessarily have to be done if there is an 9 appropriate amount of waiting.</p> <p>10 So, again, we would have to look at the 11 records and see what she was instructed and when sexual 12 activity began. And we'd also have to look at the 13 medical literature to determine are there any studies 14 out there showing when it is appropriate to regain 15 sexual activity.</p> <p>16 Q. And certainly, Doctor, you would agree with me 17 that, if a woman engages in sexual activity too soon 18 after a vaginal surgery, complications could occur?</p> <p>19 MS. GAYLE: Objection. Form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. There's -- there's too many variables there. 22 It depends upon the time of it, the health of the woman, 23 steroid status. Multiple factors come into play.</p> <p>24 Q. Is it a possibility?</p> <p>25 A. Again, I would have to look at the medical</p>	<p style="text-align: right;">Page 540</p> <p>1 true?</p> <p>2 A. That is correct, with medical literature to 3 support that.</p> <p>4 Q. Are you saying here, Doctor, that Mrs. Alonso 5 will necessarily experience depression and kill herself 6 because of the issues that she's complaining of in this 7 litigation?</p> <p>8 MS. GAYLE: Objection to form. Mischaracterizes 9 his opinions.</p> <p>10 BY THE WITNESS:</p> <p>11 A. In dealing with patients on a day-to-day 12 basis, review of the literature, being a member of the 13 International Pelvic Pain Society, one of the elite 14 societies on pelvic pain, isolation, depression due to 15 lack of physical intimacy, a guilt sensation to this can 16 possibly lead to depression, isolation, and suicide, as 17 I mentioned.</p> <p>18 Q. Did -- did you consider any other problems in 19 Mrs. Alonso's life that could contribute to the cause -- 20 I'm sorry -- that could contribute to quality-of-life 21 issues, depression, issues relating to these things 22 you've raised in your report?</p> <p>23 A. Yes. Yes, I did.</p> <p>24 Q. So did you consider her other problems such as 25 the husband being in jail who was cheating on her? Did</p>

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<p style="text-align: right;">Page 541</p> <p>1 you consider those things?</p> <p>2 MS. GAYLE: Objection, form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Oh, well, by all means. A husband being in 5 jail and those types of issues will definitely add 6 stress to her life. Compounded by the fact that she has 7 pelvic pain, that is a major issue. A husband that is 8 in jail will not cause extreme vaginal pain on my exam.</p> <p>9 Q. But you would -- do you know how long her 10 husband was in jail?</p> <p>11 MS. GAYLE: Objection. Form.</p> <p>12 BY MS. GEIST:</p> <p>13 Q. Do you know how long the couple was separated 14 because her husband was incarcerated?</p> <p>15 MS. GAYLE: Objection.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No. How long?</p> <p>18 Q. You don't know?</p> <p>19 A. I just said I don't know.</p> <p>20 Q. Okay. Well, I thought you said you read her 21 deposition.</p> <p>22 MS. GAYLE: Objection, Counsel. Mischaracterizes 23 his testimony. He's reviewed thousands of pages.</p> <p>24 BY THE WITNESS:</p> <p>25 A. I am under the understanding a deposition like</p>	<p style="text-align: right;">Page 543</p> <p>1 sometimes divorce actually improves quality of life.</p> <p>2 Q. So I don't think that answered my question, 3 though.</p> <p>4 A. It absolutely answered it.</p> <p>5 Q. Could the -- could the personal problems that 6 Mrs. Alonso has experienced in her marriage, including a 7 husband who is incarcerated for years who has cheated on 8 her, who has left her, could these issues have caused 9 her quality of life issues and depression issues 10 separate and apart from issues she says she has from the 11 Bard Avaulta product? Could she have any of those 12 issues if she never even had the Bard Avaulta product 13 implanted?</p> <p>14 A. I keep an open mind about this. That's why I 15 mentioned, women undergoing stress of a husband who is 16 cheating, who is incarcerated, and he is taken out of 17 her life could improve quality of life.</p> <p>18 Q. But could also result in a decline of quality 19 of life? You're not going to disagree with me on that, 20 are you, Doctor?</p> <p>21 MS. GAYLE: Object to form. Argumentative.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. You don't -- you don't think a woman can 24 experience depression and a decrease in quality of life 25 when she has a husband who is cheating on her and is</p>
<p style="text-align: right;">Page 542</p> <p>1 this is not a memory test. So I've asked you let's see 2 the deposition and let's go over it. If it's in there, 3 I'm very open and let's consider it. But no matter, 4 let's say he's been in prison 30 years, that will not 5 cause vaginal pain on my exam.</p> <p>6 Q. No. But a husband with an extended history of 7 incarceration could certainly cause a woman depression 8 and quality-of-life issues? Would you agree with me on 9 that?</p> <p>10 MS. GAYLE: Objection. Are you talking about 11 generally for a random person, or are you talking about 12 in a specific case?</p> <p>13 BY MS. GEIST:</p> <p>14 Q. No. I'm talking about Ms. Alonso. If 15 Mrs. Alonso was in a marriage where her husband was 16 incarcerated for five years, where she actually filed 17 for divorce, where he actually moved out, and she 18 testified he was cheating on her multiple times in the 19 marriage, could all of these things cause her to 20 experience quality-of-life issues such as depression?</p> <p>21 MS. GAYLE: Objection. Mischaracterizes 22 Mrs. Alonso's testimony and her husband's testimony.</p> <p>23 BY THE WITNESS:</p> <p>24 A. In day-to-day interaction with women in my 25 clinic, day-to-day interaction with women in the public,</p>	<p style="text-align: right;">Page 544</p> <p>1 tossed in jail for drug-related issues?</p> <p>2 MS. GAYLE: Objection. Form and mischaracterizes 3 testimony.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I could see a large number of women being 6 actually thrilled to get rid of a man in their life.</p> <p>7 Q. Could you also see a large number of women 8 experiencing depression after a husband cheats on them?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. That would be a possibly devastating part of 12 her life, and that's why she might be happy if he goes 13 off to prison.</p> <p>14 Q. Do you -- do you know the status of 15 Mrs. Alonso's marriage at this point in time? Do you 16 know whether she took him back or not?</p> <p>17 MS. GAYLE: Objection. Form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I don't recall.</p> <p>20 Q. If she took him back into the marital home 21 right before her deposition, would that change your 22 opinion on whether or not she was negatively impacted 23 when he was gone in jail for five years?</p> <p>24 MS. GAYLE: Objection. Form. Objection.</p> <p>25 Mischaracterizes his testimony.</p>

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<p>1 BY THE WITNESS:</p> <p>2 A. I could see that being a wonderful source of 3 joy, that they've reconciled themselves, and now they're 4 left with a painful vagina and they cannot engage in 5 intercourse and intimacy.</p> <p>6 Q. The dyspareunia is one of these things you 7 note with respect to Mrs. Alonso, and you attribute that 8 as well to the Bard Avaulta product, correct?</p> <p>9 A. Yes. As we mentioned earlier, the Align 10 product also goes to the exact same location as the 11 Avaulta product. It is my opinion, based upon my 12 experience, review of the literature and exam, that 13 statistically speaking with medical certainty it's going 14 to be the Avaulta product.</p> <p>15 Q. Would you agree with me, Doctor, that 16 dyspareunia is what we call sort of a nonspecific 17 complaint?</p> <p>18 MS. GAYLE: Object to form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I think it's very, very specific.</p> <p>21 Q. Are there --</p> <p>22 A. It's painful with sex -- sexual -- it is pain 23 with sexual activity, so that's very specific.</p> <p>24 Q. Are there a number of physical and 25 psychological reasons that a woman may experience</p>	<p style="text-align: right;">Page 545</p> <p>1 A. Psychological reasons can be one of the 2 considerations. However, women with stressors will not 3 have pinpoint obturator foramen tenderness and scarring 4 of the vagina.</p> <p>5 Q. Mrs. Alonso has certain stressors like what I 6 indicated to you earlier relating to a cheating husband, 7 a husband who is incarcerated. Could those contribute 8 and cause dyspareunia?</p> <p>9 A. They will not cause a scarred vagina and 10 pinpoint tenderness of the obturator foramen.</p> <p>11 Q. That wasn't my question, though. Could those 12 things cause dyspareunia? If a woman has a husband 13 who's cheated on her, and she knows it, the woman has 14 stress in her marriage because the husband is 15 incarcerated for a number of years, could those things 16 have a psychological impact on that woman and cause her 17 to experience dyspareunia?</p> <p>18 MS. GAYLE: Objection. Asked and answered.</p> <p>19 BY THE WITNESS:</p> <p>20 A. If the husband is her sole sexual partner and 21 he's in prison and not having sexual activity, they 22 won't have dyspareunia.</p> <p>23 Q. I don't think you answered my question, 24 Doctor. Can you answer my question? And my question 25 was, could those facts, as I laid them out to you, cause</p>
<p>1 dyspareunia?</p> <p>2 MS. GAYLE: Object to form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. There are multiple different things that have 5 to be and should be considered when evaluating a woman 6 for dyspareunia.</p> <p>7 Q. Many, many women experience dyspareunia who 8 have not had a transvaginal mesh implanted. Would you 9 agree with me on that?</p> <p>10 MS. GAYLE: Object to form.</p> <p>11 BY THE WITNESS:</p> <p>12 A. But then we would have to look at the 13 severity, the location, the physical exam, the 14 chronology of that.</p> <p>15 Q. Have you considered other causes for 16 Mrs. Alonso's complaints of dyspareunia?</p> <p>17 A. Absolutely. Every patient I see, on a 18 day-to-day basis, I keep an open mind to the 19 differential diagnosis of what caused it. That's why we 20 have to look at the chronology, what surgeries were 21 done, familial factors, et cetera.</p> <p>22 Q. I've seen in the literature and at least on 23 the Mayo Clinic site that dyspareunia can be caused in a 24 woman for psychological reasons. Would you agree with 25 that?</p>	<p style="text-align: right;">Page 546</p> <p>1 a woman to experience dyspareunia?</p> <p>2 MS. GAYLE: Objection. Asked and answered three 3 times now.</p> <p>4 BY THE WITNESS:</p> <p>5 A. The definition of dyspareunia is pain during 6 sexual activity. If the woman is not having sexual 7 activity, there will not be pain during sexual activity 8 because it does not exist. So the husband being 9 incarcerated, gone from the family, will not cause 10 dyspareunia. Dyspareunia -- dyspareunia can only be 11 during sexual activity. Pain during a physical exam, 12 pinpoint tenderness, scarring of the vagina exists 13 regardless of the husband's status.</p> <p>14 Q. So I still think you're not answering my 15 question. So let me try it a different way. Let's 16 assume the husband is free from jail, he's back in the 17 marital home right before the deposition, conveniently, 18 and the couple is engaging in sexual intercourse. Could 19 that history with that husband cheating, the other 20 stressors in the marriage, could that cause a woman such 21 as Mrs. Alonso to experience dyspareunia?</p> <p>22 MS. GAYLE: Objection. Asked and answered four 23 times now.</p> <p>24 BY THE WITNESS:</p> <p>25 A. Yeah. We keep going around and around with</p>

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<p style="text-align: right;">Page 549</p> <p>1 this.</p> <p>2 Q. Well, we are, Doctor, because, you know, with 3 all due respect, you're not answering my question. 4 You're avoiding it like I've never seen.</p> <p>5 A. With all due respect, I am answering it very, 6 very well based upon my experience as a surgeon in a 7 tertiary care center who takes care of these patients on 8 a day-to-day basis. A husband who comes back -- and I 9 take offense to the conveniently comes back. That is a 10 pretty negative comment to put on the record for this 11 poor woman who is suffering, who I examined. I'm the 12 only person in this room who has examined this woman. 13 I'm the only person who's talked to her and felt in the 14 vagina as far as where this pain is. And, again, maybe 15 they've reconciled and her life is good and she's happy, 16 and now she cannot become sexually active and intimate 17 and loses that segment of her life.</p> <p>18 Q. You don't -- you don't consider the 19 possibility that Mr. -- that Mrs. Alonso's husband moved 20 back in with her two weeks before the deposition for the 21 purpose of the lawsuit and what they're pursuing in the 22 lawsuit? You don't consider that as a possibility?</p> <p>23 MS. GAYLE: Object to form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. Number one, I am a surgeon here concerning her</p>	<p style="text-align: right;">Page 551</p> <p>1 A. Yeah. I would have to look at those exactly, 2 but I would not doubt they'd be similar.</p> <p>3 Q. Okay. Well, they're actually exact. We can 4 put them side by side if you want. But it's your 5 opinion, in each of these three cases, that the pelvic 6 pain and dyspareunia are highly unlikely to be resolved 7 and that these women will have these conditions for the 8 rest of their lives, correct?</p> <p>9 A. Yeah. In my experience at a tertiary medical 10 center, a member of the International Pain Society -- 11 Pelvic Pain Society with women who have come which I see 12 on a daily basis, I have yet to see one recover normal 13 sexual functions.</p> <p>14 Q. Well, you're not a pelvic pain specialist or a 15 pain specialist; is that correct?</p> <p>16 MS. GAYLE: Object to form.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Absolutely, I'm a pelvic pain specialist.</p> <p>19 Q. You are?</p> <p>20 A. This is what I do on a daily basis, yes.</p> <p>21 That's what female pelvic medicine and reconstructive 22 subspecialty approved by the boards of urogyn and 23 urology do.</p> <p>24 Q. Aren't there doctors who hold themselves out 25 as pain specialists in the medical community?</p>
<p style="text-align: right;">Page 550</p> <p>1 medical condition. The motivations behind those 2 individuals you'll have to ask them. That would be best 3 to have them answer that question.</p> <p>4 Q. You have some opinions in your report, Doctor, 5 that we talked about a little bit already with respect 6 to long-term outcome and prognosis. Do you see that in 7 your report?</p> <p>8 A. Correct.</p> <p>9 Q. And your opinions, as I understand them, is 10 that for both Mrs. Alonso's reported pelvic pain and 11 dyspareunia, you say the prognosis is poor, and it is 12 highly unlikely that Mrs. Alonso will have a complete 13 resolution of her pelvic pain and her sexual 14 dysfunction. Is that -- are those your opinions, 15 Doctor?</p> <p>16 A. Correct. In my experience at a major tertiary 17 center, with highly subspecialized training, dealing 18 with the scarred -- the vaginal scarring that takes 19 place following mesh implantation, I have yet to see one 20 woman with this severe -- with this severe of a reaction 21 ever regaining normal sexual function.</p> <p>22 Q. The -- and you have the same identical opinion 23 for Mrs. Wheeler and Mrs. Bolyard as well, correct?</p> <p>24 It's word for word in each of your three reports, this 25 section?</p>	<p style="text-align: right;">Page 552</p> <p>1 MS. GAYLE: Objection.</p> <p>2 BY THE WITNESS:</p> <p>3 A. There are anesthesiologists, usually 4 anesthesiologists, who are pain specialists, but they're 5 also urologists.</p> <p>6 Q. No. I mean doctors who actually treat people 7 experiencing chronic pain conditions, like fibromyalgia 8 and things of that nature? Aren't there doctors who are 9 considered to be pain specialists who hold themselves 10 out as pain specialists in the medical community?</p> <p>11 A. Yes, and I'm one of them.</p> <p>12 Q. You are?</p> <p>13 A. Yes.</p> <p>14 Q. You hold yourself out as a pain specialist in 15 the medical community?</p> <p>16 A. Absolutely.</p> <p>17 Q. Do you treat any other type of pain condition 18 other than pelvic pain?</p> <p>19 A. I treat only pelvic pain.</p> <p>20 Q. Do you have any particularized education, 21 training, or background or advanced degree in the 22 treatment of pain generally?</p> <p>23 A. Yes. Yes, I do. And doing a fellowship in 24 neurourology, okay, which is pelvic neuroanatomy.</p> <p>25 That's a one-year advanced training taking and passing</p>

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<p style="text-align: right;">Page 553</p> <p>1 the credentialing for female pelvic medicine and 2 reconstruction, which is dealing with pelvic pain, being 3 a member of the International Pelvic Pain Society, 4 reviewing literature, attending meetings, yeah, I have 5 an advanced level of understanding of this far more than 6 the average.</p> <p>7 Q. So you don't refer your patients out -- your 8 patients out to a pain management specialist doctor, for 9 example?</p> <p>10 A. At times I will, dependent upon my evaluation. 11 If I do not feel there is anything I can do surgically 12 for this woman, then I will -- it's a multispecialty 13 approach. I at times will get my urogynecology 14 colleagues involved. I will get colorectal involved. I 15 may get -- sometimes if they're going to do injections 16 into the spine. I don't do that. I'll get multiple 17 people involved because this is a multispecialty 18 approach to dealing with this problem.</p> <p>19 Q. You don't perform trigger-point injections or 20 anything of that nature to address complaints of pain; 21 is that true?</p> <p>22 A. No. I deal more with the surgical management 23 of the pelvic pain, medication management of the pelvic 24 pain. When it comes time to do injections, I have other 25 subspecialists who I feel can treat these individuals</p>	<p style="text-align: right;">Page 555</p> <p>1 therapists within my department. I also have physical 2 medicine, rehab physical therapists that I deal with. 3 Q. Did -- when you met with Mrs. Alonso, did you 4 refer her to a physical therapist or a pain management 5 specialist?</p> <p>6 A. I make no -- I was very clear with them. I am 7 here to evaluate you. I made no medical 8 recommendations. I gave her no diagnosis. I told her 9 upfront, I am here to evaluate you to come up with an 10 opinion on my own, but I did not talk to her about 11 diagnosis, prognosis, or treatment options.</p> <p>12 Q. And, by the way, Doctor, can we agree that all 13 of these questions and answers you're providing me on 14 this issue of permanency of the pelvic pain and 15 dyspareunia, that they would also apply -- your same 16 responses would apply to Mrs. Wheeler and Mrs. Bolyard's 17 cases?</p> <p>18 A. Yeah. I agree completely unless there is some 19 other nuance that pops up.</p> <p>20 Q. Understood.</p> <p>21 A. But you're right.</p> <p>22 Q. Understood. Do you know whether Mrs. Alonso 23 has sought the assistance from a pain management 24 specialist?</p> <p>25 A. I would have to go back and look at the</p>
<p style="text-align: right;">Page 554</p> <p>1 and have a better chance of it.</p> <p>2 Q. So a pain management specialist would be a 3 doctor you would refer your patients to if they're going 4 to look into the option of trigger-point injections, for 5 example, to manage pain?</p> <p>6 MS. GAYLE: Objection. Asked and answered.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I need for you to define trigger-point 9 injections then.</p> <p>10 Q. You don't know what I mean when I use that 11 term?</p> <p>12 MS. GAYLE: Objection. Mischaracterizes his 13 testimony.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Trigger points -- there are trigger points in 16 the spine. There's trigger points in the neck. There's 17 migraine trigger points. So you have to define what 18 you're talking about. I will not do a trigger-point 19 injection for migraines.</p> <p>20 Q. In reaching your diagnosis, your opinions 21 about the long-term prognosis for Mrs. Alonso, did you 22 consider the availability of physical therapy for the 23 pain?</p> <p>24 A. Absolutely. That is one of the other 25 individuals in my armamentarium. I have physical</p>	<p style="text-align: right;">Page 556</p> <p>1 records. Off the top of my head, I do not recall.</p> <p>2 Q. How about Mrs. Wheeler and Mrs. Bolyard? Do 3 you know whether they have sought care and treatment 4 from a pain specialist, pain management specialist, 5 pardon me?</p> <p>6 A. It's the same answer for all of those.</p> <p>7 Q. You don't know whether any of those plaintiffs 8 are seeing a pain management doctor?</p> <p>9 A. I don't recall.</p> <p>10 Q. In Mrs. Alonso's case, did you consider, in 11 reaching your differential diagnosis, whether there were 12 any -- strike that.</p> <p>13 In Mrs. Alonso's case, did you consider, in 14 reaching your differential diagnosis, the surgical 15 technique of the implanting doctor, Dr. Suarez?</p> <p>16 A. Absolutely.</p> <p>17 Q. The Avaulta -- the Bard Avaulta mesh is 18 supposed to be implanted tension-free. Do you 19 understand that?</p> <p>20 A. Correct.</p> <p>21 Q. And that's set forth in the IFU for the 22 product? Can we agree on that?</p> <p>23 A. I would have to look because I'd have to 24 refresh my memory on the IFU; however, it is well-known 25 and established that it should be placed tension-free.</p>

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<p>Page 557</p> <p>1 Q. Okay.</p> <p>2 A. But the definition of tension-free is unknown.</p> <p>3 Q. Understood. But that's not something that you</p> <p>4 think would be unknown to an implanting doctor. It's</p> <p>5 well-established the mesh needs to be implanted</p> <p>6 tension-free, and that's in order to allow for the</p> <p>7 tissue ingrowth that is expected with the products; is</p> <p>8 that true?</p> <p>9 A. No. It depends upon when the implantation</p> <p>10 took place. In the early years, when there was no</p> <p>11 experience with meshes, no one knew what the right</p> <p>12 amount of tension would be.</p> <p>13 Q. How about --</p> <p>14 A. In --</p> <p>15 Q. I'm sorry. Go ahead.</p> <p>16 A. In 2014 -- well, it's not available. Let's</p> <p>17 say when it was last available on the market, it would</p> <p>18 be a more -- there is a lot more data out there on what</p> <p>19 tension-free would be. Now, the reason for tension-free</p> <p>20 is because of contraction of the mesh to account for it.</p> <p>21 Q. There is a certain degree of contraction due</p> <p>22 to the normal wound healing process after a transvaginal</p> <p>23 mesh is implanted. Is that correct?</p> <p>24 A. Yes. If we looked at various different data,</p> <p>25 Letourzney was the one that comes to mind,</p>	<p>Page 559</p> <p>1 A. Again, I would have to see that note because</p> <p>2 I'd have to look at the note in its entirety.</p> <p>3 Q. Understood. But as -- and I'm asking you to</p> <p>4 assume what is true as I've just stated to you, and then</p> <p>5 we'll look at the note. But if the note describes that</p> <p>6 the mesh was put in under tension and without proper</p> <p>7 tacking to prevent migration and curling, would that be</p> <p>8 proper surgical technique?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. I would like to look at that note and then</p> <p>12 I'll decide whether I agree with you or not.</p> <p>13 MS. GAYLE: Let's take a quick bathroom break,</p> <p>14 Counsel, if you don't mind.</p> <p>15 MS. GEIST: Yeah. Let's take a quick break.</p> <p>16 That's a good idea.</p> <p>17 VIDEO TECHNICIAN: We're off the record. The time</p> <p>18 is 10:39 a.m.</p> <p>19 (A recess was had.)</p> <p>20 VIDEO TECHNICIAN: We're back on the record. The</p> <p>21 time is 10:55 a.m.</p> <p>22 (Elliott Deposition Exhibit Nos. 30 &</p> <p>23 31 were marked for identification.)</p> <p>24 BY MS. GEIST:</p> <p>25 Q. Dr. Elliott, let me hand you what I've marked</p>
<p>Page 558</p> <p>1 L-E-T-O-U-R-Z-N-E-Y, et al., after six months, up to 80</p> <p>2 percent contraction.</p> <p>3 Q. Now, Dr. Suarez implanted Mrs. Alonso's</p> <p>4 Avaulta product on July 19, 2010. Do you understand</p> <p>5 that?</p> <p>6 A. July 19th, 2010, I agree.</p> <p>7 Q. Okay. So, at that point in time, was it</p> <p>8 well-known in the medical community that the</p> <p>9 transvaginal mesh product needed to be implanted</p> <p>10 tension-free in your opinion?</p> <p>11 A. I can't say as far as that date. That's in</p> <p>12 the middle years of this, so I can't say.</p> <p>13 Q. Do you know if the IFU at the time instructed</p> <p>14 the implanting doctor to implant the mesh tension-free?</p> <p>15 A. I would have to look at that IFU and then also</p> <p>16 have to know what IFU Dr. Suarez was looking at, too.</p> <p>17 Q. Did you look at the operative note from</p> <p>18 Dr. Suarez's surgery?</p> <p>19 A. Yes. I reviewed it closely. I don't recall</p> <p>20 it right now. I would like to see it. That would be</p> <p>21 helpful.</p> <p>22 Q. If the operative note describes that the mesh</p> <p>23 was put in under tension without proper tacking to</p> <p>24 prevent migration and curling, would that have been</p> <p>25 proper surgical technique?</p>	<p>Page 560</p> <p>1 during a break as Exhibit 30 and 31 to your deposition.</p> <p>2 And, for the record, Exhibit 30 is the Avaulta Plus</p> <p>3 Biosynthetic Support System IFU dated at the bottom</p> <p>4 October of 2009. And Exhibit 31 is the operative report</p> <p>5 by Dr. Suarez for Mrs. Alonso for the surgical procedure</p> <p>6 performed on July 19th, 2010.</p> <p>7 Let me hand those to you and give a copy to</p> <p>8 your counsel. This is 30 and this is 31.</p> <p>9 MS. GAYLE: Thank you.</p> <p>10 BY MS. GEIST:</p> <p>11 Q. Doctor, directing your attention to Exhibit</p> <p>12 30, which is the IFU for the Avaulta Plus Biosynthetic</p> <p>13 Support System?</p> <p>14 A. Yes.</p> <p>15 Q. You've reviewed this before the deposition,</p> <p>16 correct?</p> <p>17 A. Yes, I have.</p> <p>18 Q. Okay. And if you go with me to the fourth</p> <p>19 page of the document --</p> <p>20 A. I'm there.</p> <p>21 Q. -- under Description, on the second paragraph,</p> <p>22 it states, The monofilament polypropylene mesh used in</p> <p>23 the Avaulta Plus Biosynthetic Support System has a soft</p> <p>24 knit in the central section for compliant organ support</p> <p>25 and host tissue ingrowth, and a strong knit in the</p>

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<p style="text-align: right;">Page 561</p> <p>1 lateral sides to provide improved strength for 2 tension-free fixation of the mesh. Do you see that?</p> <p>3 A. Oh, here we go.</p> <p>4 Q. I'm sorry. Were you --</p> <p>5 A. I was -- no, no. I list- --</p> <p>6 Q. Were you not with me when I was reading?</p> <p>7 A. No. I was listening to you.</p> <p>8 Q. Okay.</p> <p>9 A. Okay. Yes. Yes.</p> <p>10 Q. We were talking about whether or not the IFU 11 contained information and instructions for a physician 12 regarding the fact that the mesh should be placed 13 tension-free, correct?</p> <p>14 A. I agree that's what you stated, but that's not 15 what this states. It never states placed tension-free.</p> <p>16 Q. Right. Well, I haven't gotten -- I haven't 17 gotten through the IFU yet.</p> <p>18 A. Okay. Yes.</p> <p>19 Q. I'm just noting this section for you. Okay?</p> <p>20 A. Okay. I will agree with you that that's what 21 this states in this section, but it doesn't say anything 22 about placed.</p> <p>23 Q. Okay. And this IFU would have been in effect 24 for Mrs. Alonso's operation because that operation was 25 January 19th, 2010, correct?</p>	<p style="text-align: right;">Page 563</p> <p>1 Q. I'm not asking you to agree that this is the 2 version used by Dr. Suarez. We already talked to 3 Dr. Suarez about that.</p> <p>4 A. Okay.</p> <p>5 Q. I'm just saying you don't have any reason, 6 sitting here today, to disagree with me that this is 7 probably the version he used. I'm not asking you to 8 agree with me. Do you understand that?</p> <p>9 A. Yeah. I cannot attest to what version. He 10 would know what version he read. That's all I'm saying. 11 I just can't say it.</p> <p>12 Q. That's fine. That's fine. And if you go with 13 me to -- we just finished looking at page 4. If you 14 flip to page 5, in all bold, in caps, it says, Implant 15 procedures. Do you see that?</p> <p>16 A. Yes, I see that.</p> <p>17 Q. And then there is a section regarding 18 preparation of Avaulta Plus mesh for implantation, 19 correct?</p> <p>20 A. That is correct.</p> <p>21 Q. And that provides information to the surgeon 22 regarding what should be done prior to implantation by 23 way of summary, true?</p> <p>24 A. That is correct.</p> <p>25 Q. And then -- and then it has a section in bold</p>
<p style="text-align: right;">Page 562</p> <p>1 A. This IFU was in circulation. I don't know 2 what IFU Dr. Suarez was using.</p> <p>3 Q. Okay. Fair enough. But, as you look at the 4 document, it has a date at the bottom of October 2009 on 5 the first page, correct?</p> <p>6 A. October of 2009 is when this came out, yes.</p> <p>7 Q. You don't have any reason, sitting here today, 8 to believe that this was the version of the IFU that was 9 used by Dr. Suarez when he implanted the Avaulta mesh in 10 Mrs. Alonso about a year later?</p> <p>11 MS. GAYLE: Objection. Asked and answered.</p> <p>12 BY THE WITNESS:</p> <p>13 A. I will agree that this was in circulation. I 14 will not agree that that's the version that Dr. Suarez 15 used. Because if the company came to his office, took 16 out all of his old IFUs, and replaced it with the new 17 ones, then I would agree, but I have no support of that.</p> <p>18 Q. Do you know whether or not an IFU accompanies 19 each and every Bard Avaulta system that is sold and 20 provided to a medical doctor?</p> <p>21 A. I cannot attest to that. IFUs are usually 22 included, but I don't know what version of -- if he does 23 not do very many of these, perhaps, he's using a product 24 that was, you know, sitting on the shelves for a year 25 because these have long shelf lives.</p>	<p style="text-align: right;">Page 564</p> <p>1 for implantation techniques for the Avaulta Plus 2 Biosynthetic Anterior Support System, correct?</p> <p>3 A. Correct. And I'm trying to correlate that.</p> <p>4 For my understanding, Alonso had the Avaulta Solo put in 5 her or did she have the Avaulta Classic? Because based 6 upon the operative note, I don't believe it actually 7 states it. I would have to look at what the -- from the 8 records, what he actually -- because I don't recall 9 which one was placed in her.</p> <p>10 Q. You don't recall which product Mrs. Alonso had 11 implanted in her by Dr. Suarez?</p> <p>12 A. No. That's what I'm saying. I would want to 13 clarify to make sure we're all on the same page.</p> <p>14 Q. Okay. If you turn with me to page 6 of 15 Exhibit 30 that we're looking at together --</p> <p>16 A. Yes.</p> <p>17 Q. -- No. 5?</p> <p>18 A. Yes.</p> <p>19 Q. If you -- oh, I'm sorry. I'm on the wrong 20 number, No. 6. Number 6 says, Apply traction. It says 21 a number of things, and then the second sentence in 22 No. 6 says, Be sure the graft is tension-free. Do you 23 see that?</p> <p>24 A. Yes. I am reading over that sentence right 25 now.</p>

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<p style="text-align: right;">Page 565</p> <p>1 Q. Okay. This is the second part in the IFU that 2 talks about the graft being tension-free?</p> <p>3 A. Correct. With no clarifier what tension-free 4 actually means.</p> <p>5 Q. And then at No. 9, if you go with me to No. 9, 6 it has sort of a next step in the surgical procedure, if 7 you will. And on the sixth line down, it says, ensure 8 the central graft is positioned under the bladder 9 without extensive -- excessive tension. Do you see 10 that, Doctor?</p> <p>11 A. Yes, I see that.</p> <p>12 Q. So that's the third time the IFU is talking 13 about not implanting the graft with tension?</p> <p>14 A. No.</p> <p>15 Q. It should be tension-free?</p> <p>16 A. I'm sorry. I interrupted you. That's my 17 fault. No. I disagree with you on the second. Under 18 point No. 9 of the IFU, it says, without excessive 19 tension. That means there is tension. There's not 20 excessive tension. That's different than tension-free. 21 I completely agree with you on Point No. 6. It states 22 tension-free. But point No. 9, it's very clear without 23 excessive tension.</p> <p>24 Q. And then, if you go with me to No. 10 on the 25 next page, it says, The mesh should be sufficiently</p>	<p style="text-align: right;">Page 567</p> <p>1 A. Well, I think statistically speaking twice 2 they say avoid excessive tension. One time they say 3 tension-free. So, again, those are -- they're ambiguous 4 terms.</p> <p>5 Q. You think they're ambiguous?</p> <p>6 A. Yeah. I don't know what excessive tension, if 7 I -- I am someone, an individual putting these in, 8 excessive tension means I make it tight, but I just 9 don't make it really tight. I don't know what that 10 means.</p> <p>11 Q. You've never implanted one of these devices as 12 we've talked about yesterday, correct?</p> <p>13 A. I have not implanted, in a live human being, 14 an Avaulta Plus.</p> <p>15 Q. Do you know if Dr. Suarez thought these 16 instructions were vague or ambiguous in any way?</p> <p>17 MS. GAYLE: Objection.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I would have -- I would have to look at his 20 deposition. I don't recall what he said.</p> <p>21 Q. Do you think if a doctor, a surgeon about to 22 use the product, thought that these instructions were 23 vague or ambiguous in any way, do you think that doctor 24 could ask for further information or clarification from 25 Bard?</p>
<p style="text-align: right;">Page 566</p> <p>1 anchored to stabilize it during tissue ingrowth. So 2 that indicates the anticipated and normal sequence of 3 tissue ingrowth in the mesh product, true?</p> <p>4 MS. GAYLE: Objection. Form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. To me that's telling me they're trying to 7 prevent a way to keep this thing from folding and 8 scarring up.</p> <p>9 Q. And then the second sentence says, Additional 10 sutures may be used to secure the mesh tension-free. Do 11 you see that?</p> <p>12 A. Yes. And then it goes down below. It says, 13 Caution, excessive tension should be avoided. Again, it 14 doesn't say tension-free. It says excessive tension.</p> <p>15 Q. Right. So that was my next point to you. And 16 then there's a caution underneath No. 10. And, it 17 reads, as you've started to indicate, Caution, excessive 18 tension should be avoided on the mesh and suture 19 attachment points to account for wound shrinkage during 20 the healing process. Did I read that correctly?</p> <p>21 A. That is what they state.</p> <p>22 Q. So the IFU for the Bard Avaulta product 23 indicates that it should be tension-free. It should be 24 implanted tension-free and excessive tension should be 25 avoided?</p>	<p style="text-align: right;">Page 568</p> <p>1 MS. GAYLE: Objection. Form. Calls for 2 speculation.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I think it leaves open the room for a surgeon 5 looking at this and says, who is doing their due 6 diligence and reading over this, says avoid excessive 7 tension. Okay. I'll avoid excessive tension. But it 8 doesn't say what excessive tension is. Does it say it 9 would be nice if they prevent the tissues from being 10 bent or pressure on the tissue? But, again, it just 11 says excessive tension.</p> <p>12 Q. Would you agree with me, Doctor, obviously, if 13 a surgeon about to implant this device has any sort of 14 ambiguity or it's unclear to that doctor what he or she 15 needs to do, that that doctor should ask the question 16 before implanting the device, that would be good medical 17 practice?</p> <p>18 MS. GAYLE: Objection. Form. Speculation.</p> <p>19 BY THE WITNESS:</p> <p>20 A. But if -- if the doctor has done their work, 21 they feel comfortable doing their procedure, then they 22 read this, without objective data, they won't 23 necessarily know what excessive tension is.</p> <p>24 Q. Well, and if they don't, they should ask a 25 question of the device manufacturer, correct?</p>

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<p style="text-align: right;">Page 569</p> <p>1 A. No. But excessive tension might be then they 2 might think about it and say, Okay, I see that. Let's 3 make sure this is not cranked up really high so that the 4 bladder is elevated up significantly. I will prevent 5 that. I won't put excessive tension on it.</p> <p>6 Q. Would you agree with me that it's the 7 responsibility of a pelvic floor surgeon to understand 8 proper surgical technique when implanting a medical 9 device?</p> <p>10 A. I agree with you completely. And what I'm 11 saying is, without objective data to go off of, this is 12 subjective. And they may look at it. They may think 13 about it. They're doing the responsible thing. They 14 say, okay, I'll avoid excessive tension. That's 15 subjective. It's not an objective term.</p> <p>16 Q. If you look with me to what we've marked as 17 Exhibit 31, that's the operative report for Dr. Suarez 18 for the surgical procedure on Mrs. Alonso on July 19th, 19 2010?</p> <p>20 A. Correct.</p> <p>21 Q. And have you looked at this document before, 22 Dr. Elliott?</p> <p>23 A. Yes. When I did the original IME, I reviewed 24 this.</p> <p>25 Q. Okay. Does this document indicate to you that</p>	<p style="text-align: right;">Page 571</p> <p>1 have to answer what that means.</p> <p>2 Q. Is there any indication in the operative</p> <p>3 report that he used any type of tacking or sutures to</p> <p>4 prevent any migration or curling of the mesh?</p> <p>5 A. No. That's why I stated. I do not see, in 6 his note -- it does not appear that he recorded anything 7 about tacking it down. He would be the best one to 8 answer that question, not me. But I do not -- to answer 9 your question, I do not see it in the note.</p> <p>10 Q. And if the implanting surgeon, Dr. Suarez, 11 didn't use any sutures or other methods for tacking it 12 down, that may, in fact, have resulted in migration or 13 erosion or curling of the mesh, true?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. It would not affect the arms of the mesh. The 17 proximal or distal portion of it, possibly. But I don't 18 know. I have not heard any data or seen any studies 19 whether or not tacking actually correlates to any 20 success. All I can state is, in this note, it does not 21 appear he did any tacking stitches.</p> <p>22 Q. Would you agree with me that it's possible 23 that due to the lack of tacking of the mesh, that that's 24 why Mrs. Alonso experienced issues with exposure or 25 erosion?</p>
<p style="text-align: right;">Page 570</p> <p>1 Dr. Suarez implanted the mesh under tension and without 2 any proper tacking to prevent migration or curling of 3 the mesh?</p> <p>4 A. Let me read over it here. Okay. I've 5 finished reading it. I had to determine what segment 6 was what because obviously he performed two different 7 procedures. So the first paragraph of the description 8 of the procedure is the POP, the pelvic organ prolapse. 9 The second part appears to be the urethral sling.</p> <p>10 Q. And, after reading this, Doctor, does this 11 indicate to you that Dr. Suarez implanted the mesh under 12 tension and did not use any type of tacking as indicated 13 in the IFU to prevent any migration or curling of the 14 mesh?</p> <p>15 MS. GAYLE: Objection. Form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. I do not see, in the dictation, that he states 18 that it was tacked down. Regard- -- so that's point 19 number one. Regarding the tension placed on it, he's 20 using the term vaginal tape, which I'm understanding 21 that is the Avaulta mesh, applied positive pressure 22 against the posterior bladder wall. So I don't -- I 23 don't know what he means by that, applied positive 24 pressure against it. So not to avoid you, I just don't 25 know what that means. He would be the one who would</p>	<p style="text-align: right;">Page 572</p> <p>1 MS. GAYLE: Objection. Form. Objection.</p> <p>2 Mischaracterizes evidence.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I can't -- again, I would have to -- important 5 to go off of what the data is out there. I don't know 6 of any data out there, objective studies, showing that 7 that makes a difference at all. It does not correlate 8 to what the IFU states. But does that correlate it to 9 real life? I don't know that.</p> <p>10 Q. The surgical technique followed by Dr. Suarez 11 is not consistent with what the IFU instructs as you 12 just said, correct?</p> <p>13 MS. GAYLE: Objection. Form. Mischaracterizes his 14 testimony.</p> <p>15 BY THE WITNESS:</p> <p>16 A. On that one aspect of not placing the tacking 17 stitches, that was not done as is stated in the IFU. 18 Whether or not that correlates to complications, I can't 19 answer that.</p> <p>20 Q. Did you -- so then you didn't consider that 21 issue, Dr. Suarez's surgical technique which is contrary 22 to the IFU, in reaching your opinions with respect to 23 Mrs. Alonso's complications?</p> <p>24 MS. GAYLE: Objection. Form. Objection,</p> <p>25 mischaracterizes his testimony. And objection,</p>

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<p>1 mischaracterizes the evidence.</p> <p>2 BY THE WITNESS:</p> <p>3 A. No. What I can state is, I cannot go off of</p> <p>4 objective studies, papers looking at whether or not</p> <p>5 tacking down correlates to any of those issues as</p> <p>6 discussed in the IFU.</p> <p>7 Q. Can you tell me whether or not it's possible</p> <p>8 it could have resulted in some of the complications</p> <p>9 experienced by Mrs. Alonso?</p> <p>10 MS. GAYLE: Objection. Form. Objection. As I've</p> <p>11 stated before, mischaracterizes evidence.</p> <p>12 Mischaracterizes testimony. Mischaracterizes</p> <p>13 Dr. Suarez's testimony. And the witness would like</p> <p>14 knowledge. Just because this one page doesn't have it</p> <p>15 on there does not mean that it's not in evidence</p> <p>16 elsewhere.</p> <p>17 BY THE WITNESS:</p> <p>18 A. To answer your question, I have no objective</p> <p>19 data whether or not tacking actually plays a role in</p> <p>20 folding, erosion, extrusion.</p> <p>21 Q. Well, Doctor, I'm not -- I'm not a doctor, and</p> <p>22 I wouldn't pretend to be a medical doctor. But tacking</p> <p>23 is included as an instruction in the IFU. And if one</p> <p>24 doesn't tack down the mesh, even a layperson could</p> <p>25 understand that it may move or fold or roll, aren't</p>	<p>Page 573</p> <p>1 report beginning on the bottom of page 8 and going to</p> <p>2 page 11?</p> <p>3 A. Correct. Okay.</p> <p>4 Q. Okay. So, just for the record, beginning on</p> <p>5 page 8, on the entirety of page 9, the entirety of Page</p> <p>6 10, and then maybe half of page 11, this is about two</p> <p>7 and a half pages of all of the things you think that</p> <p>8 Bard should have included in the IFU for the Avaulta</p> <p>9 product. Is that a fair summary?</p> <p>10 A. That's correct.</p> <p>11 Q. And that's your opinion, that all of the</p> <p>12 things on two and a half pages here in your report,</p> <p>13 should have been included in the IFU?</p> <p>14 A. That is correct.</p> <p>15 Q. And I think it's also your opinion that</p> <p>16 Mrs. Alonso was not able to make an informed decision</p> <p>17 about her use of transvaginal mesh because Bard failed</p> <p>18 to disclose these risks?</p> <p>19 A. I say it's a combination of things that,</p> <p>20 because Dr. Suarez was not fully informed, subsequently</p> <p>21 he was not able to fully inform Mrs. Alonso.</p> <p>22 Q. Okay. And it's your opinion that, if</p> <p>23 Dr. Suarez was informed in the IFU of all of these</p> <p>24 risks, then he would have been better able to inform</p> <p>25 Mrs. Alonso; is that your opinion?</p>
<p>Page 574</p> <p>1 those possibilities, things that may occur, if a mesh is</p> <p>2 not properly tacked down as instructed in the IFU?</p> <p>3 MS. GAYLE: Object to form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I disagree completely because I am a surgeon</p> <p>6 and I have read the IFUs and the studies on other</p> <p>7 products like Prolift, Apogee, and they have nothing</p> <p>8 about tacking down. And their products have very high</p> <p>9 incidence of erosion, scarring, and things. So just</p> <p>10 because this one says it, I don't know.</p> <p>11 Also, I have a lot of data showing impaired</p> <p>12 healing with the presence of any polypropylene,</p> <p>13 especially if there is collagen. So I have data for</p> <p>14 that. What I'm saying is, I have no data to go off of</p> <p>15 that tacking down the mesh changes the erosion. If you</p> <p>16 have data, I would like to see it. I will keep an open</p> <p>17 mind.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. Let me -- let me move, Doctor, to page 8 of</p> <p>20 your report, if you have your expert report in front of</p> <p>21 you.</p> <p>22 A. I have it here.</p> <p>23 Q. And, again, Doctor, I'm going to try and</p> <p>24 summarize, for purposes of efficiency, your opinions</p> <p>25 which are contained in Mrs. Alonso's case-specific</p>	<p>Page 575</p> <p>1 A. If he were fully aware of the frequency and</p> <p>2 the severity and the permanence of these complications,</p> <p>3 including, you know, all that's listed there, he would</p> <p>4 have been able to better inform Mrs. Alonso who would</p> <p>5 then have been able to better make a decision.</p> <p>6 Q. Now, you say, on page 8, at the bottom, that</p> <p>7 all of the risks that you list on the next two and a</p> <p>8 half pages were known, but Mrs. Alonso was not informed</p> <p>9 of these risks on her informed consent. Do you see</p> <p>10 that?</p> <p>11 A. Okay. I'm sorry. You're on the bottom of</p> <p>12 page 8.</p> <p>13 Q. I'm on the bottom of page 8.</p> <p>14 A. The paragraph starting with since Bard knew;</p> <p>15 is that correct?</p> <p>16 Q. Correct.</p> <p>17 A. Okay. I'm sorry. Can you repeat the</p> <p>18 question?</p> <p>19 Q. Sure. So, in the last sentence of this</p> <p>20 paragraph, you say, The following lists of risks that</p> <p>21 were known, but Mrs. Alonso was not informed of on her</p> <p>22 informed consent, correct?</p> <p>23 A. Correct. That's what it states.</p> <p>24 Q. Did you look at the informed consent in</p> <p>25 Mrs. Alonso's case as part of your review of her medical</p>

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<p>1 records?</p> <p>2 A. Yes. I was sent that.</p> <p>3 Q. And there was no information on an informed 4 consent about the risk of erosion or pain or dyspareunia 5 associated with the Avaulta product, true?</p> <p>6 MS. GAYLE: Objection.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I'd have to see that informed consent. I 9 can't recall that one.</p> <p>10 Q. Whose responsibility is it to provide the 11 informed consent; Bard's, a medical device manufacturer, 12 or the doctor, Dr. Suarez, in this case?</p> <p>13 A. The informed consent is based upon -- the 14 informed consent is based upon the information that the 15 surgeon has gained from multiple different sources, 16 including the IFU.</p> <p>17 Q. Okay. So it's not -- you would agree with me 18 it's not Bard's responsibility to put particular 19 language in an informed consent. The doctor drafts the 20 informed consent for his or her patient, true?</p> <p>21 A. I disagree with that. Bard has a 22 responsibility to provide to the doctors all known risks 23 regardless of severity and to list them for the doctor. 24 The doctor's then responsibility is to take that 25 information, to trust it being accurate, and then to</p>	<p>Page 577</p> <p>1 A. Mentions the same thing, yes. The doctor has 2 to take all of the available data that is provided to 3 him from the company and then inform the patient.</p> <p>4 Q. So let's assume that all of the information on 5 the two and a half pages that you have here in your 6 report was provided by Bard to Dr. Suarez. Okay?</p> <p>7 A. I'm supposed to assume that?</p> <p>8 Q. Yeah. Let's assume that. Let's assume all of 9 the information that you say should have been put in the 10 IFU for the Avaulta product was provided by Bard to 11 Dr. Suarez?</p> <p>12 A. If all of those, however many --</p> <p>13 MS. GAYLE: I'm sorry. There's --</p> <p>14 BY MS. GEIST:</p> <p>15 Q. There is no question yet.</p> <p>16 MS. GAYLE: There is no question pending, Doctor.</p> <p>17 BY MS. GEIST:</p> <p>18 Q. Just assume -- just assume with me all of that 19 information was given to Dr. Suarez, okay?</p> <p>20 A. Okay.</p> <p>21 Q. And all of this information on the two and a 22 half pages you say, Dr. Elliott, is information that 23 Bard knew about and Bard purposely didn't put it in the 24 IFU, didn't communicate it to doctors; is that a fair 25 summary? Bard should have done this, Bard knew about</p>
<p>1 properly inform the patient.</p> <p>2 Q. So the doctor's responsibility is to put 3 together the informed consent and provide the 4 risk-benefit analysis to the patient. That's the 5 doctor's role, correct? I mean, there's nothing 6 controversial about what I'm asking you here. That's 7 the doctor's role?</p> <p>8 A. The doctor's role is just as I stated. The 9 doctor has to take all available information on a 10 product and surgery and then to adequately inform and 11 thoroughly inform the patient.</p> <p>12 Q. All right. So I think we're saying the same 13 thing. You don't expect Bard to be sitting down with a 14 particular patient and talking about the particular 15 risks and benefits of the medical device. The doctor's 16 role is to have that conversation with his or her 17 patient. Do you agree with me on that?</p> <p>18 A. Yeah. Bard's role is to provide all known 19 complications regardless of severity, and then the 20 doctor's role is to be in the room alone with the 21 patient and family. Bard has no role inside that office 22 interaction.</p> <p>23 Q. Right. It's the doctor's job to obtain the 24 informed consent from his or her patient for the 25 surgical procedure, correct?</p>	<p>Page 578</p> <p>1 these risks and didn't communicate it to doctors?</p> <p>2 MS. GAYLE: Objection. Form.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Yeah. You're asking me to assume something, 5 and then I'm kind of not following you because it's a 6 complicated question. You're asking me to assume Bard 7 told everybody and I lost you.</p> <p>8 Q. Yeah. Let me go back. You're saying that 9 Bard knew about all of these risks and Bard should have 10 informed Dr. Suarez, or any other doctor, about all of 11 these risks, Bard failed to do this, Bard knew certain 12 information, and they failed to put it in the IFU?</p> <p>13 A. They failed to adequately put it in the IFU. 14 I'll agree with that.</p> <p>15 Q. Okay. On that point, Doctor, did you ever 16 review any FDA regulations or rules on what needs to go 17 into an IFU before getting involved in this litigation?</p> <p>18 MS. GAYLE: Objection to that question. That was 19 covered yesterday in his general testimony.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. That wasn't specifically. The question was, 22 before you got involved in this litigation, did you ever 23 review any FDA rules or regulations relating to what 24 should or should not be put into a medical device 25 instructions for use?</p>

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<p style="text-align: right;">Page 581</p> <p>1 MS. GAYLE: Objection. Again, I believe that was 2 covered yesterday.</p> <p>3 BY THE WITNESS:</p> <p>4 A. Do I answer? I mean --</p> <p>5 Q. It's a different question, and I'm happy to 6 compare the transcripts. But the question was specific. 7 Before this litigation, had you ever read or acquainted 8 yourself with the FDA rules and regulations regarding 9 what information needs to be put or not included in an 10 IFU?</p> <p>11 MS. GAYLE: You may answer that question subject to 12 my objection.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I guess I'm somewhat confused. I thought 15 yesterday was the -- all of this. Now we're going back 16 to the general report. I can't recall all of the 17 documents. I'm involved in reviewing 30 different IFUs. 18 I can pull up the notes as far as what IFUs I reviewed. 19 I can't recall when I first saw FDA guidelines. You 20 know, in 2008, when the first FDA warning came out, I 21 reviewed the things then. In 2011, I reviewed it. 22 So I can't recall when I first became aware of 23 various different FDA -- I'm sure, over the course of 24 this litigation, my understanding of the regulation 25 process has increased. I'm not going to deny that. I</p>	<p style="text-align: right;">Page 583</p> <p>1 first looked at any, like the FDA Blue Book. I don't 2 know when that first was. I wouldn't be able to tell 3 you with any specific accuracy. That FDA Blue Book is 4 available online.</p> <p>5 Q. And you can't tell me whether or not you first 6 looked at that before you got involved as an expert in 7 the litigation?</p> <p>8 MS. GAYLE: Objection. Asked and answered and 9 discussed yesterday. I'm going to instruct him not to 10 go over this territory, which was went over yesterday. 11 I think we're burning time on this issue and it's 12 duplicate. And, you know, Judge Goodwin does not like 13 duplicative testimony.</p> <p>14 BY MS. GEIST:</p> <p>15 Q. It's not. I never asked you yesterday about 16 did you review any FDA regulations, rules or guidance, 17 before you got involved as an expert in the litigation. 18 I did not ask that question yesterday. That's why I'm 19 asking it today.</p> <p>20 MS. GAYLE: And it should have been answered, 21 Counsel, because that's a general question that went to 22 his general opinions yesterday. We covered the Blue 23 Book yesterday. He answered questions. If you failed 24 to ask a question yesterday, it's our position that it's 25 a question that's lost because it was a general</p>
<p style="text-align: right;">Page 582</p> <p>1 don't recall when I first saw what was required. I was 2 always under the impression everything had to be told to 3 the doctor on the IFU.</p> <p>4 Q. And I understand your impression, but my 5 question was, before you got involved as an expert for 6 plaintiffs in the pelvic mesh litigation, did you ever 7 go and review and research the FDA regulations, rules 8 and guidance documents, about what needs to go into a 9 label or not?</p> <p>10 MS. GAYLE: My objection is reiterated. Again, I 11 think this goes to yesterday's testimony as well as 12 another objection because he's asked and answered the 13 question.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Okay. As of day one of medical school 16 residency staff, I was -- and I'll answer your question. 17 I was under the understanding the IFU had to tell me 18 everything about the product. That was my 19 understanding. Then, as I got involved in this 20 litigation and looking at various different things and 21 digging deeper, then I'm finding out that that 22 understanding was correct.</p> <p>23 However, again, in 2008 and 2011, when the FDA 24 started coming out with these warnings, that's when I 25 started looking into this. So I can't tell you when I</p>	<p style="text-align: right;">Page 584</p> <p>1 question. You can't rehash general today when he's 2 sitting here on case specifics. You're not asking him 3 anything about the Blue Book in relation to these three 4 plaintiffs.</p> <p>5 MS. GEIST: Well, I'm going to object. You should 6 make your objection to form. If you want to raise it in 7 a motion, that's fine. Speaking objections are not 8 allowed. We went through this yesterday with other 9 counsel.</p> <p>10 And this is a specific point in Dr. Elliott's 11 case-specific report that goes on for four pages. And 12 it's specifically tied to Mrs. Alonso, because 13 Dr. Elliott opines, in his report, that all of these 14 risks should have been in the IFU and Mrs. Alonso was 15 not informed of these risks because Bard failed to 16 provide these risks to her surgeon, Dr. Suarez.</p> <p>17 MS. GAYLE: And we'll just take it up in motion 18 practice.</p> <p>19 MS. GEIST: That's fine.</p> <p>20 MS. GAYLE: But, again, our objection is 21 reiterated. This is a general opinion. If you have 22 opinions to these people, ask a question to these 23 people.</p> <p>24 BY MS. GEIST:</p> <p>25 Q. And that's what this is all about,</p>

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<p style="text-align: right;">Page 585</p> <p>1 Mrs. Alonso. So can you answer my last question, 2 Doctor?</p> <p>3 MS. GEIST: If the court reporter could read it 4 back for him.</p> <p>5 BY THE WITNESS:</p> <p>6 A. No. I recall the question. You're asking me 7 to speculate. If I had to give a time frame of first 8 looking into specific FDA regulations, that would be 9 when I was contacted by Dr. Michael Carome of Public 10 Citizen because he was getting involved as far as 11 drafting that copy to the F- -- yeah, to the FDA. And 12 that's probably when I first would have looked at that 13 document. And that was in -- it was signed in August. 14 That process started, probably, in June, June of 2011.</p> <p>15 Q. Thank you. So, now, Doctor, getting back to 16 my original question, let's assume that all of the 17 information that you say Bard knew about and, therefore, 18 should have put in the IFU, this two and a half pages, 19 let's assume, for the purposes of this question, that 20 Dr. Suarez was informed by Bard of everything you lay 21 out here in your two and a half pages. Okay?</p> <p>22 A. Okay.</p> <p>23 Q. Can you assume that for me?</p> <p>24 A. I can assume that, yes.</p> <p>25 Q. Okay. Even if all of this information was</p>	<p style="text-align: right;">Page 587</p> <p>1 BY THE WITNESS: 2 A. I cannot speculate what Dr. Suarez would do. 3 I can speculate -- I -- beyond speculate, I could tell 4 you what I would do and what a reasonable colleague of 5 mine would do. I can't speak for Dr. Suarez. 6 Dr. Suarez would be the best one to answer that 7 question.</p> <p>8 Q. Well, you told me you read Ms. Alonso's 9 deposition testimony, right?</p> <p>10 A. Correct.</p> <p>11 Q. Do you recall her testimony that she was not 12 informed of any of the risks associated with 13 transvaginal mesh?</p> <p>14 A. I do recall her saying that. In my 15 experience, sometimes individuals forget things over 16 time. I know what she stated.</p> <p>17 Q. Well, would you agree with me that there is 18 nowhere in Dr. Suarez's records or the informed consent 19 to establish that he provided her with any of the risks 20 of the implantation of transvaginal mesh to Mrs. Alonso?</p> <p>21 MS. GAYLE: Objection, form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. That's why I stated earlier I would want to 24 see, again, the clinical notes and specifically the 25 informed consent. And then that also does not entail</p>
<p style="text-align: right;">Page 586</p> <p>1 provided to Dr. Suarez, how do you know, to a reasonable 2 degree of medical probability or certainty, that 3 Dr. Suarez would have provided any of that information 4 to Mrs. Alonso?</p> <p>5 A. Well, you're asking me to theorize. You're 6 asking me, number one, to make a huge assumption that 7 Dr. Suarez would have provided -- been provided an 8 honest evaluation of risks, lifelong complications, and 9 a reasonable doctor would have then relayed that on to 10 patients. I cannot speak for him. I would have told 11 the patients all of that data because I wanted a fully 12 informed patient. I cannot speculate what Dr. Suarez 13 would do. That would be a best question for him.</p> <p>14 Q. So, sitting here today, you can't say that had 15 Bard provided all of this information to Dr. Suarez, 16 Dr. Suarez would have provided it to Mrs. Alonso?</p> <p>17 MS. GAYLE: Objection. Form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. I can't speak to what Dr. Suarez would do. I 20 can speak to what I would do and what I feel a 21 reasonable surgeon would do.</p> <p>22 Q. Can we agree, Dr. Elliott, that Dr. Suarez 23 likely would not have provided all of this information 24 to Mrs. Alonso?</p> <p>25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 588</p> <p>1 what actually went on in the office. And if he were 2 under the impression, after reading the IFU, that these 3 risks are minimal, he might have downplayed it.</p> <p>4 Q. Did you see any evidence in the records that 5 Dr. Suarez talked to Mrs. Alonso about risks like 6 erosion, pelvic pain, and dyspareunia associated with 7 the implant of a transvaginal mesh product?</p> <p>8 A. Yeah. I don't recall, and that's why I'm 9 asking to see those records again so we can go over 10 that, what was done on multiple clinic visits and at the 11 formal informed consent.</p> <p>12 Q. So I just want to make sure I'm clear. There 13 is no -- you don't have any evidence, sitting here 14 today, Dr. Elliott, that Dr. Suarez would have passed on 15 any of this information that you say should have been 16 included in the IFU?</p> <p>17 MS. GAYLE: Objection.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. That he would have passed any of it on to 20 Mrs. Alonso?</p> <p>21 MS. GAYLE: Object.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. Would you agree with me?</p> <p>24 MS. GAYLE: Objection, form. Objection, 25 mischaracterizes evidence.</p>

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<p>1 BY THE WITNESS:</p> <p>2 A. Well, all I can state -- again, I cannot speak</p> <p>3 for Dr. Suarez. He is the one who needs to address that</p> <p>4 question. A reasonable surgeon would relay on to a</p> <p>5 patient, if he or she is fully knowledgeable of all of</p> <p>6 the risks, you have to relay all of those risks to the</p> <p>7 patient.</p> <p>8 Q. Well, would a reasonable surgeon relay to a</p> <p>9 patient who is considering having a transvaginal mesh</p> <p>10 device implanted in her body, would a reasonable surgeon</p> <p>11 talk about risks such as erosion, pain, and dyspareunia?</p> <p>12 A. I can speak for myself. I would.</p> <p>13 Q. And those are all risks that are in the Bard</p> <p>14 Avaulta IFU, are they not?</p> <p>15 A. I would have to look at the IFU and see how</p> <p>16 they state it. Because if -- if a surgeon is looking at</p> <p>17 his frame of reference being native procedures and he</p> <p>18 sees pain, he's thinking and correlating that to native</p> <p>19 procedures, which is short-term, so pain, dyspareunia,</p> <p>20 all of those things. So, again, I can't speak to what</p> <p>21 that surgeon's frame of reference is. Again, he would</p> <p>22 be the best one to answer that.</p> <p>23 Q. Well, referring back to the IFU that we marked</p> <p>24 as Exhibit 30, Doctor, under Adverse Reactions, on page</p> <p>25 5 of the IFU, the Adverse Reactions section of the IFU</p>	<p>Page 589</p> <p>1 deposition. You were prepared to come here and talk</p> <p>2 about Mrs. Alonso's case, correct?</p> <p>3 A. Yes. I had over a thousand pages of documents</p> <p>4 to review, and I cannot remember every single word. And</p> <p>5 so that's why I would like to just see what was stated</p> <p>6 on his informed consent.</p> <p>7 Q. So, sitting here now, you can't tell me</p> <p>8 whether or not Dr. Suarez informed Mrs. Alonso of at</p> <p>9 least some of the risks that are included here in the</p> <p>10 adverse reaction section of the IFU?</p> <p>11 A. I have the understanding a deposition is not</p> <p>12 memory test. This is very detailed issues, and that's</p> <p>13 why I would like to see the informed consent. It seems</p> <p>14 fairly basic. I asked for the operative report and I</p> <p>15 got that. And so I would like to see the informed</p> <p>16 consent and then we can logically go through it. And</p> <p>17 then I can disagree -- or, excuse me, agree or disagree</p> <p>18 with you.</p> <p>19 Q. If -- if Dr. Suarez did not inform Mrs. Alonso</p> <p>20 of some of the potential adverse events or complications</p> <p>21 associated with transvaginal mesh, would that be acting</p> <p>22 within the standard of care?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. I don't know as far as standard of care. The</p>
<p>Page 590</p> <p>1 from Bard informs a surgeon that complications</p> <p>2 associated even with the proper implantation of the</p> <p>3 Avaulta Plus Biosynthetic Support System include, and</p> <p>4 what's listed below are a number of different things.</p> <p>5 And what's included is extrusion, erosion, inflammation,</p> <p>6 pain, dyspareunia, scarification, among other things.</p> <p>7 Those are all -- all included in the adverse reaction</p> <p>8 section of the IFU, true?</p> <p>9 A. Yeah. But, see, we're limited. It talks</p> <p>10 about extrusion, but it does not talk about lifelong</p> <p>11 risk of extrusion. It does not give you any qualifiers</p> <p>12 of the extent and the severity of the problem.</p> <p>13 Q. Understood. But there is no evidence in this</p> <p>14 case, from the informed consent documents or the records</p> <p>15 from Dr. Suarez, that Dr. Suarez even told Mrs. Alonso</p> <p>16 about the potential risks of erosion, pain, or</p> <p>17 dyspareunia?</p> <p>18 MS. GAYLE: Objection.</p> <p>19 BY MS. GEIST:</p> <p>20 Q. Do you agree with me?</p> <p>21 A. Again, I would have to see that -- those</p> <p>22 records. I don't recall that specific terminology. I</p> <p>23 would have to look at the records.</p> <p>24 Q. Well, Doctor, we don't have time for you to go</p> <p>25 through all of the records again here at your</p>	<p>Page 592</p> <p>1 purpose of an informed consent is to inform the patient</p> <p>2 of risks and have them consent or not.</p> <p>3 Q. So -- all right. So setting aside standard of</p> <p>4 care, if Mrs. Alonso's testimony is true that Dr. Suarez</p> <p>5 didn't tell her about any of the potential risks</p> <p>6 associated with the implantation of Bard's Avaulta</p> <p>7 product, that would be something you would be critical</p> <p>8 of with respect to Dr. Suarez?</p> <p>9 MS. GAYLE: Object to form. Objection,</p> <p>10 mischaracterizes evidence and testimony.</p> <p>11 BY MS. GEIST:</p> <p>12 Q. I mean, would that be proper medical care and</p> <p>13 counseling to a patient if Dr. Suarez did not, in fact,</p> <p>14 obtain informed consent from Mrs. Alonso prior to the</p> <p>15 procedure?</p> <p>16 A. In discussion with patients on a daily basis</p> <p>17 and providing informed consents to patients on a daily</p> <p>18 basis, unfortunately, not everybody remembers all of the</p> <p>19 issues that are discussed with them. So, therefore,</p> <p>20 that's why I'd have to go down to the -- what the notes</p> <p>21 say and what Dr. Suarez says in his deposition.</p> <p>22 MS. GEIST: Can we go off the record one</p> <p>23 minute?</p> <p>24 VIDEO TECHNICIAN: We're off the record. The time</p> <p>25 is 11:35 a.m.</p>

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<p style="text-align: right;">Page 593</p> <p>1 (A short recess was had.)</p> <p>2 VIDEO TECHNICIAN: We're back on the record. The</p> <p>3 time is 11:37 a.m.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. Dr. Elliott, had Mrs. Alonso had a native</p> <p>6 tissue repair to resolve her pelvic organ prolapse or an</p> <p>7 abdominal sacrocolpopexy procedure, would you agree with</p> <p>8 me that she could have experienced the same issues with</p> <p>9 pelvic pain and dyspareunia?</p> <p>10 A. No. I disagree.</p> <p>11 Q. You disagree. She didn't have -- she wouldn't</p> <p>12 have had any risk of pelvic pain or dyspareunia after</p> <p>13 having a native tissue repair; is that your testimony?</p> <p>14 A. No. My testimony is you have to put the</p> <p>15 qualifiers on the location, the degree, the severity,</p> <p>16 the inability to cure it. And with a sacrocolpopexy, we</p> <p>17 are talking about -- excuse me, with a mesh repair,</p> <p>18 we're talking about midvault scarring of the obturator</p> <p>19 foramen. The sacrocolpopexy is not even in that region.</p> <p>20 The same thing with the native tissue repair. So I</p> <p>21 would -- you would have to put the qualifiers on it.</p> <p>22 Q. Okay. Well, let me try and put the qualifiers</p> <p>23 on it. If Mrs. Alonso had had a native tissue repair,</p> <p>24 would you agree with me that she still could have</p> <p>25 experienced pelvic pain and dyspareunia?</p>	<p style="text-align: right;">Page 595</p> <p>1 had a native tissue repair or an ASC, an abdominal</p> <p>2 sacrocolpopexy, she could have still experienced some</p> <p>3 degree of pelvic pain and dyspareunia, true?</p> <p>4 MS. GAYLE: Objection. Form. Mischaracterizes his</p> <p>5 testimony.</p> <p>6 BY THE WITNESS:</p> <p>7 A. To a minor and, in my experience, correctible</p> <p>8 extent and short-lived and, as far as impact upon</p> <p>9 quality of life, minimal, she could have had some</p> <p>10 discomfort.</p> <p>11 Q. Is it your opinion, Doctor, that every woman</p> <p>12 who has had a native tissue repair or an ASC and who has</p> <p>13 experienced pelvic pain and dyspareunia as a result of</p> <p>14 those surgeries has always had short-term and</p> <p>15 correctible pelvic pain and dyspareunia?</p> <p>16 MS. GAYLE: Objection. Form.</p> <p>17 BY MS. GEIST:</p> <p>18 Q. There is no risk of long-term pelvic pain or</p> <p>19 dyspareunia with either of those surgical procedures?</p> <p>20 MS. GAYLE: Objection. Form. Mischaracterizes his</p> <p>21 testimony and asked and answered yesterday as well as</p> <p>22 today.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I can state, in my practice now, at a</p> <p>25 high-volume tertiary center with highly subspecialized</p>
<p style="text-align: right;">Page 594</p> <p>1 A. In my experience, in a high-volume tertiary</p> <p>2 center, a member of the International Pelvic Pain</p> <p>3 Society, she has the chance of having mild and usually</p> <p>4 correctible -- and, in my experience, I have never had</p> <p>5 one of permanent -- dyspareunia. That is comparing to</p> <p>6 mesh, which is permanent, progressive, and severe.</p> <p>7 Q. So she could have still experienced pelvic</p> <p>8 pain and dyspareunia, but it's your opinion that the</p> <p>9 pelvic pain and dyspareunia she's complaining of now is</p> <p>10 more severe and permanent in nature; is that right?</p> <p>11 A. It is more severe. Based upon the data and my</p> <p>12 experience, it's progressive. There is no ability to</p> <p>13 cure it. So with those qualifiers on there, then I</p> <p>14 agree with you.</p> <p>15 Q. And you're certainly not going to give an</p> <p>16 opinion that had Mrs. Alonso had a native tissue or an</p> <p>17 ASC procedure, that she would have had no risk of</p> <p>18 experiencing pelvic pain or dyspareunia? You would</p> <p>19 never give that opinion, would you?</p> <p>20 A. I would give the opinion that, in my</p> <p>21 experience, I've never once had an individual with this</p> <p>22 severe of pain in this location and in a progressive</p> <p>23 nature. And in our review of sacrocolpopexies, we've</p> <p>24 had zero incidence of pelvic pain.</p> <p>25 Q. So the answer to my question is, yes, had she</p>	<p style="text-align: right;">Page 596</p> <p>1 care that I have never once seen an individual with a</p> <p>2 native tissue or sacro- -- or sacrocolpopexy procedure</p> <p>3 present with severe, debilitating, progressive pain like</p> <p>4 I see with the transvaginal mesh kits.</p> <p>5 Q. But you're aware, from the literature, if not</p> <p>6 your own personal experience, that women who have had</p> <p>7 native tissue and ASC repairs experience pelvic pain and</p> <p>8 dyspareunia years after those procedures are done?</p> <p>9 You're aware of that, correct?</p> <p>10 MS. GAYLE: Continuing objection. Can I have that</p> <p>11 so I don't have to keep interrupting you on this line of</p> <p>12 questioning? I believe you asked and answered this</p> <p>13 yesterday, Counsel.</p> <p>14 BY MS. GEIST:</p> <p>15 Q. Well, I'm focusing on Mrs. Alonso.</p> <p>16 A. My statement stands as from yesterday and</p> <p>17 today. And what I've reiterated is you have to put the</p> <p>18 qualifiers on there of the severity, the progressive</p> <p>19 nature of it, the life-changing disability. I have</p> <p>20 never once, at a high-volume tertiary care center, seen</p> <p>21 that. Especially important when you look at the various</p> <p>22 different papers out there from Karram, Zimmerman,</p> <p>23 Blandon, that we discussed, where they're saying that</p> <p>24 these mesh complications require tertiary care.</p> <p>25 So I am not seeing the need for these -- for</p>

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<p style="text-align: right;">Page 597</p> <p>1 tertiary, advanced-level care with these women who 2 received those other types of native repair or 3 sacrocolpopexy.</p> <p>4 Q. So Mrs. Alonso is complaining of pelvic pain 5 and dyspareunia a few years after her mesh implant 6 procedure, correct?</p> <p>7 A. That is correct.</p> <p>8 Q. And is it not established in the literature 9 that women who had a native tissue or ASC repair 10 complain of pelvic pain and dyspareunia years after 11 those procedures as well?</p> <p>12 A. Again, we keep leaving off those qualifiers. 13 If you give me those qualifiers on there, severe, 14 progressive, debilitating, without a source of cure, 15 then I will agree with you.</p> <p>16 Q. Had Mrs. Alonso had a transvaginal mesh device 17 implanted by another manufacturer, would you agree with 18 me, Dr. Elliot, that she could have experienced pelvic 19 pain and dyspareunia as a result of that procedure?</p> <p>20 MS. GAYLE: Objection. Form.</p> <p>21 BY THE WITNESS:</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 599</p> <p>1 opinion, if she had the Avaulta Plus, she's at the 2 highest risk possible of complication with the 3 transvaginal mesh kit.</p> <p>4 Q. Understood. But we agree that had she used 5 another medical device company's mesh kit, she still 6 could have had the same complications?</p> <p>7 MS. GAYLE: Objection.</p> <p>8 BY MS. GEIST:</p> <p>9 Q. Are we in agreement on that?</p> <p>10 MS. GAYLE: Objection, form. And objection, calls 11 for speculation.</p> <p>12 BY THE WITNESS:</p> <p>13 A. I mean, I think I answered it very well the 14 last time. And, actually, I would like to know. I 15 would like to see in the records, because we must have 16 it somewhere -- I just don't have it off the top of my 17 head -- which product she had put in there. So if she 18 had the Plus or not, because that would help us out. 19 Because if she had the Plus, I will then state that she 20 is at a higher risk for complications.</p> <p>21 Q. Understood. But she still would have been at 22 risk for the same complications if she had been 23 implanted with another medical device's -- another 24 medical device company's pelvic mesh kit product, true?</p> <p>25 MS. GAYLE: Objection. Form. Counsel, are you</p>
<p style="text-align: right;">Page 598</p> <p>1 A. And that is theoretical; however, if you look 2 at the data out there, Prolift, Apogee, Perigee, 3 Pinnacle, SIS, severe debilitating pain occurs with 4 those other mesh devices as well as Avaulta.</p> <p>5 Q. Okay. So, sitting here today, you can't say 6 that Mrs. Alonso's outcome would have been any different 7 had she been implanted with another transvaginal mesh 8 device?</p> <p>9 MS. GAYLE: Objection.</p> <p>10 BY MS. GEIST:</p> <p>11 Q. Is that true?</p> <p>12 MS. GAYLE: Objection. Form and objection calls 13 for speculation and --</p> <p>14 BY THE WITNESS:</p> <p>15 A. That's not necessarily true because remember I 16 just cannot recall, from the literature -- or not, 17 excuse me, not the literature, the medical records which 18 specific Avaulta product she had placed. If she had the 19 Plus, then she has collagen on there so there could be a 20 higher rate of complications with it. The arms are 21 heavier weight with the Avaulta product regardless of 22 which one it is.</p> <p>23 So I cannot say she would not -- it gets 24 confusing. There is a very good risk she still would 25 have had complications with another mesh kit. In my</p>	<p style="text-align: right;">Page 600</p> <p>1 talking about the same exact complications 2 percentagewise, different? What?</p> <p>3 BY MS. GEIST:</p> <p>4 Q. Could Mrs. Alonso still have experienced 5 pelvic pain and dyspareunia if she had been implanted 6 with another medical device company's transvaginal mesh?</p> <p>7 That's my question.</p> <p>8 A. My opinion is transvaginal polypropylene mesh 9 for pelvic organ prolapse is bad across the board. Had 10 she had another product in there like Prolift, which 11 there's hundreds and hundreds of papers out on Prolift, 12 perhaps, even more than that, clearly shows devastation 13 in women. Apogee, Perigee, the same thing. Pinnacle, 14 the same thing. And, again, there is another product 15 out there. I can't recall off the top of my head.</p> <p>16 So, yes, she could have had devastating 17 complications with that. My argument is, is that the 18 Avaulta mesh, the arms are heavyweight, small pore, 19 which data shows that Klosterhalfen and Cobb, et al., 20 higher rates of complications with those. And, if she 21 had collagen, there's data that show those have impaired 22 healing. So I am -- I am partly agreeing with you, 23 again, with the clarifications in this as I answered 24 here.</p> <p>25 Q. If -- if Mrs. Alonso's transvaginal mesh was</p>

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<p style="text-align: right;">Page 601</p> <p>1 made from a different grade of polypropylene other than 2 the Marlex polypropylene used in the Avaulta products, 3 can you state, to a reasonable degree of medical 4 certainty, that she would not have experienced pelvic 5 pain and dyspareunia?</p> <p>6 MS. GAYLE: Objection, form. Objection, calls for 7 speculation and assumes facts not in evidence.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Yeah. I'm sorry. Like, as far as a different 10 grade, you'd have to tell me the weight of it, the pore 11 size, all of those different factors. Right now, as far 12 as I know, the Marlex that is used has heavyweight arms. 13 And so, again, polypropylene, in my -- my opinion, based 14 upon my evidence and my experience and what we had 15 mentioned over and over and over, should not be placed 16 in the vagina on women for pelvic organ prolapse.</p> <p>17 Q. But it's okay for the midurethral sling, 18 correct?</p> <p>19 MS. GAYLE: Objection.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. As we talked about yesterday?</p> <p>22 MS. GAYLE: Objection. Form. Objection. 23 Mischaracterizes testimony and goes into general 24 opinions from yesterday.</p> <p>25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 603</p> <p>1 clarify, was in response to this specific patient. And 2 so we're not replowing general opinions from yesterday.</p> <p>3 MS. GEIST: Right. We're talking about this 4 specific patient.</p> <p>5 MS. GAYLE: It's your question. We're doing 6 specifics.</p> <p>7 BY MS. GEIST:</p> <p>8 Q. In this specific patient, we already talked 9 about the fact that she has the Align sling implanted at 10 the same time that she had the Avaulta Plus or Solo 11 product implanted, and we don't know which one it is, 12 right?</p> <p>13 A. Correct. I know what the Align sling was. We 14 know that. That's very clear.</p> <p>15 Q. But not which Bard POP product?</p> <p>16 A. No. I do not recall what that one is, and the 17 operative note does not state it.</p> <p>18 Q. And --</p> <p>19 A. And those were done at the same procedure, 20 July 19th, 2010.</p> <p>21 Q. And the Align sling that Mrs. Alonso had 22 implanted was implanted for the purpose of correcting 23 her stress urinary incontinence, correct?</p> <p>24 A. Correct.</p> <p>25 Q. That's the indication for that medical device?</p>
<p style="text-align: right;">Page 602</p> <p>1 A. No. What I just said, I had the qualifiers on 2 there on purpose. The Align sling is heavyweight, small 3 pore, which we have data from Cobb, Klosterhalfen, are 4 the two I can remember off the top of my head. My 5 report has many more. There are known, very clear 6 complications from that with degradation, contraction, 7 pain, et cetera. So I personally, in my practice, do 8 not implant any transvaginal mesh.</p> <p>9 Q. But you understand, and I don't want to replow 10 yesterday at all, but you understand that other pelvic 11 floor surgeons continue to believe in and implant the 12 midurethral polypropylene sling like the Align product, 13 and you haven't come out and sent a separate letter to 14 the FDA seeking the removal of that type of product from 15 the market like you did with the POP products, true?</p> <p>16 MS. GAYLE: Objection. I'm going to instruct him 17 not to answer that as that is exactly replowing 18 yesterday.</p> <p>19 MS. GEIST: Well, the doctor brought it up. I 20 think it's legitimate. If he's going to raise it, then 21 I can ask a question in response. So I would like to 22 have an answer subject to your objection.</p> <p>23 MS. GAYLE: But you, yourself, admitted that was 24 replowing yesterday and it was a general question. And 25 so I think his answer or his question, and he can</p>	<p style="text-align: right;">Page 604</p> <p>1 A. Correct.</p> <p>2 Q. And there is no evidence, in Mrs. Alonso's 3 medical records, that she's had any recurrence of stress 4 urinary incontinence, true?</p> <p>5 MS. GAYLE: Objection. Form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. On my discussion with the patient, and I 8 believe I go over that here. I have to find it as I say 9 currently. Yeah. Under my exam, as I recall -- here we 10 go -- she had mild urethral hypermobility with no SUI 11 noted. However, her bladder was empty at the time of 12 the examination. So on my exam, on that day, I did not 13 elicit any urinary incontinence.</p> <p>14 Q. And there is nothing in her records reflecting 15 any stress urinary incontinence either, true, since --</p> <p>16 A. I --</p> <p>17 Q. -- since the implant of the Bard Align 18 product?</p> <p>19 A. I do not recall that being a problem that she 20 had mentioned, no.</p> <p>21 Q. So, in other words, the Bard Align sling 22 product is doing exactly what it was intended to do, 23 treat and resolve the stress urinary incontinence 24 problems Mrs. Alonso is experiencing?</p> <p>25 MS. GAYLE: Objection. Form.</p>

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<p>1 BY THE WITNESS:</p> <p>2 A. Yeah, I don't -- I do not recall any mention 3 regarding stress urinary incontinence.</p> <p>4 Q. So, in other words, the product worked? It's 5 doing what it was intended to do, correct?</p> <p>6 MS. GAYLE: Objection. Form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I don't believe anybody is going to challenge 9 whether or not a product, a given sling product, can 10 treat stress incontinence. It's the complications from 11 that sling product which are the issue.</p> <p>12 Q. But in her case, Mrs. Alonso's case, we've 13 already talked about this extensively, you're 14 attributing all of her complications to the Bard Avaulta 15 product, the POP product and not the sling product, 16 true?</p> <p>17 A. No.</p> <p>18 MS. GAYLE: Objection. Form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. No. What I've stated, and we'd need to go 21 back to exactly what I stated, I'll paraphrase it. The 22 Avaulta Align -- excuse me, the Align transobturator 23 sling, which is heavyweight, small pore, goes through 24 the obturator foramen in essentially the exact location 25 as the Avaulta mesh.</p>	<p style="text-align: right;">Page 605</p> <p>1 you had to eat, so --</p> <p>2 THE WITNESS: And I have a flight at 5:15, which 3 will take me 25 minutes to get there.</p> <p>4 MS. GAYLE: Well, she said that these will be 5 shorter, so...</p> <p>6 THE REPORTER: Can we go off?</p> <p>7 MS. GEIST: Yeah. Let's go off the record.</p> <p>8 VIDEO TECHNICIAN: We're off the record. The time 9 is 11:53 a.m.</p> <p>10 (A recess was had.)</p> <p>11 VIDEO TECHNICIAN: We're back on the record. The 12 time is 12:15 p.m.</p> <p>13 BY MS. GEIST:</p> <p>14 Q. So, Dr. Elliott, we just had a very quick 15 lunch break and let's continue on with your opinions in 16 the case of Martina Wheeler. Okay?</p> <p>17 A. Okay.</p> <p>18 Q. And, Doctor, we've previously marked your 19 notice of deposition, and that actually applies to the 20 three cases in which you've given a specific report, 21 Mrs. Alonso, Mrs. Wheeler, and Mrs. Bolyard. And that's 22 Exhibit 28, correct?</p> <p>23 A. Yes. Correct. That is correct.</p> <p>24</p> <p>25</p>
<p>1 So, on my exam, she has severe pain in that 2 region and scarring. Statistically speaking, due to the 3 larger volume of mesh with meaning, you know, the arms 4 of the Avaulta, statistically speaking, it is more 5 likely than not to be due to the Avaulta than the Align, 6 period.</p> <p>7 Q. Okay. Doctor, I want to move on to 8 Mrs. Wheeler now. Do you want to take a break?</p> <p>9 A. No.</p> <p>10 Q. And how about the court reporter?</p> <p>11 A. She's fine. She's happy. She's happy to be 12 here. Do you need a break?</p> <p>13 Q. I think we're all happy to be here, Doctor, 14 but I need to just go to the court reporter because she 15 has the hardest job of all of us.</p> <p>16 A. She's nodding. She's fine.</p> <p>17 Q. She is?</p> <p>18 A. Yes, she went like that. (Indicating.)</p> <p>19 Q. I can't tell.</p> <p>20 MS. GAYLE: Lunch?</p> <p>21 THE WITNESS: Do you need a break?</p> <p>22 MS. GAYLE: Can we take a short, like maybe ten 23 minutes lunch break.</p> <p>24 MS. GEIST: Yes.</p> <p>25 MS. GAYLE: Madame Court Reporter, I know you said</p>	<p style="text-align: right;">Page 606</p> <p>1 (Elliott Deposition Exhibit No. 33 2 was marked for identification.)</p> <p>3 BY MS. GEIST:</p> <p>4 Q. And I've marked as Exhibit 33 your 5 case-specific report in Mrs. Wheeler's case. And, as 6 I -- I'm sorry. As I indicated to you earlier, Doctor, 7 I'm not going to ask you the same generally applicable 8 questions that we just went through with respect to 9 Mrs. Alonso's case. Okay.</p> <p>10 And, with respect to your opinions in 11 Mrs. Wheeler's case, is it fair to say that you formed 12 your opinions in that case using the same methodology 13 that you used in Mrs. Alonso's case?</p> <p>14 A. Correct. As I outlined earlier, it would be 15 the same process.</p> <p>16 Q. Okay?</p> <p>17 MS. GAYLE: Counsel, just for the record, you 18 handed me what's Exhibit 33, and that does not have his 19 exhibit attachments to that. I just wanted to note that 20 for the record.</p> <p>21 MS. GEIST: Thank you. And I was -- I was actually 22 going to get to that.</p> <p>23 BY MS. GEIST:</p> <p>24 Q. And your attachments to Mrs. Wheeler's report 25 I didn't bring with me separately because they're the</p>

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<p style="text-align: right;">Page 609</p> <p>1 same. They have your CV and your materials relied list. 2 The only difference would be case-specific materials and 3 records relating to Mrs. Wheeler, correct?</p> <p>4 A. Correct, yes.</p> <p>5 Q. And you have that in the version that you're 6 looking at now?</p> <p>7 A. Yeah. This is my copy highlighted with one 8 set of notes, but I can just rely off yours. That was 9 just for efficiency's sake.</p> <p>10 Q. Okay. And let's just make sure we're all 11 clear that that is a final copy of the report.</p> <p>12 A. Oh.</p> <p>13 MS. GAYLE: He's not going to rely -- he's not 14 going to look at it.</p> <p>15 THE WITNESS: Yes.</p> <p>16 MS. GAYLE: Because I have not taken the time to -- 17 this one is the final copy that you handed me, your 18 Exhibit 33, but I took away from him his earlier copies 19 because, honestly, I only did a line-by-line comparison 20 of one and found that it's a draft. But for 21 efficiency's sake, I just took everything away from him. 22 He was just asking if he should highlight for efficiency 23 purposes like you allowed him to do earlier, but we're 24 good.</p> <p>25 THE WITNESS: And I don't need to. We -- yeah.</p>	<p style="text-align: right;">Page 611</p> <p>1 Q. And, just as I did with you, Doctor, with 2 Mrs. Alonso, I just want to summarize the opinions you 3 have in Mrs. Wheeler's case, okay?</p> <p>4 A. Okay.</p> <p>5 Q. So in terms of her symptomatology, in your 6 opinion, she experiences pelvic pain, pelvic floor 7 myalgia, urge incontinence, dyspareunia, and similarly 8 loss of quality of life, which may have a long-term 9 impact. Is that a fair summary?</p> <p>10 A. That is correct.</p> <p>11 Q. Okay. And, in Mrs. Wheeler's case, she was 12 implanted with the Avaulta Solo products to treat both 13 an anterior and a posterior defect, correct?</p> <p>14 A. And, yes, she had Avaulta Solo posterior 15 Avaulta Solo anterior, and an Align TOT for 16 incontinence.</p> <p>17 Q. Similarly, Doctor, in your opinions with 18 respect to Mrs. Alonso, you don't have any opinions that 19 the Align sling was the predominant cause or substantial 20 cause of the complaints that Mrs. Wheeler has; is that 21 correct?</p> <p>22 MS. GAYLE: Objection. Form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Same as my testimony with Alonso, that, based 25 upon my experience, statistics, data, available</p>
<p style="text-align: right;">Page 610</p> <p>1 We're good with that.</p> <p>2 BY MS. GEIST:</p> <p>3 Q. Okay. So with Mrs. Wheeler, in forming your 4 opinions with respect to her case, Doctor, did you do a 5 differential diagnosis?</p> <p>6 A. Yes. As outlined previously in the Alonso 7 case, I used the same process, same differential 8 diagnosis, same consideration, keeping an open mind of 9 all possibilities.</p> <p>10 Q. Okay. And the alternative possibilities or 11 medical conditions or causes of the issues complained of 12 by Mrs. Wheeler are not specifically set forth in any 13 list that I can read in your report in Mrs. Wheeler's 14 case, true?</p> <p>15 A. No. It is exactly as outlined in my testimony 16 on Alonso. The same process, the same options were 17 considered and ruled out with the exception of with 18 Wheeler of the Osler-Weber-Rendu syndrome as indicated 19 in my report on page 2. That would be a unique 20 diagnosis that Ms. Alonso obviously did not have.</p> <p>21 Q. And you considered that in reaching your 22 opinion that that did not contribute in any way to 23 Mrs. Wheeler's complaints; is that correct?</p> <p>24 A. Correct. I have no logical evidence that that 25 was playing a role in her outcome.</p>	<p style="text-align: right;">Page 612</p> <p>1 manuscripts, and internal documentation, statistically 2 speaking, the Avaulta Solo anterior would be responsible 3 for what I found on my exam, much more so than the 4 Align.</p> <p>5 Q. Okay. And just so we're clear, there's no 6 opinions with respect to the Bard Align sling product in 7 your report for Mrs. Wheeler, correct?</p> <p>8 MS. GAYLE: Objection. Form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I do not -- I do not state anything along 11 those lines in my report.</p> <p>12 Q. Okay. And she was implanted with the Avaulta 13 and Align products by Dr. Sprock on July 7th, 2008, 14 correct?</p> <p>15 A. That is what my records reflect, yes.</p> <p>16 Q. And we already discussed that she was 17 implanted with the Avaulta Solo products, correct?</p> <p>18 A. Correct. Solo anterior and posterior.</p> <p>19 Q. So your opinions with respect to the Avaulta 20 Plus products, which are a collagen/polypropylene 21 combination product, any of those opinions would not 22 apply in Mrs. Wheeler's case; is that fair to say?</p> <p>23 A. With the exception that the arms of the Solo 24 are the same, high-density, small pore. The issues 25 pertaining to collagen and the hypersensitivity, et</p>

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<p style="text-align: right;">Page 613</p> <p>1 cetera, do not apply to Mrs. Wheeler.</p> <p>2 Q. On -- okay. So, Doctor, let me start by 3 asking you whether you considered a number of different 4 things with respect to Mrs. Wheeler in reaching your 5 differential. Okay?</p> <p>6 A. Okay.</p> <p>7 Q. In concluding or opining that the Bard Avaulta 8 products were the cause for her dyspareunia and pelvic 9 pain, did you consider the fact that Mrs. Wheeler is in 10 her mid-50s and menopausal?</p> <p>11 A. Yes. That is always a consideration. The 12 hormonal status at age 50 -- actually, the hormonal 13 status is going to be still fairly decent.</p> <p>14 Q. Isn't it true, Doctor, that there could be 15 significant pain or dyspareunia associated with 16 intercourse in a woman whose vagina is atrophic -- 17 atrophic? Pardon me.</p> <p>18 MS. GAYLE: Objection. Form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Again, we have to put the qualifiers on there. 21 Atrophic vaginal perimenopausal, post-menopausal can 22 contribute to vaginal dryness that is usually amenable 23 to a vaginal lubricant. So it's a different type, 24 quality, severity of pain.</p> <p>25 Q. Well, vaginal atrophy or vaginal thinning due</p>	<p style="text-align: right;">Page 615</p> <p>1 high-volume tertiary center, subspecialized in female 2 pelvic medicine, fully board-certified in that, my 3 opinion was she was well-estrogenized.</p> <p>4 Q. Excuse me. Are you aware of whether 5 Mrs. Wheeler has been taking estrogen therapy for a 6 number of years to treat the vaginal atrophy?</p> <p>7 A. I can't recall specifically. Most women have 8 been treated with estrogen from time to time for 9 extrusion. So I would have to see with that.</p> <p>10 Q. In reaching your opinion that she experiences 11 now severe dyspareunia, did you take into consideration 12 her medical records where she reports that her 13 dyspareunia is mild?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. Did you see that in any of the medical records 17 for Mrs. Wheeler?</p> <p>18 A. Yeah. I've seen various medical records and 19 documentation. All I can speak to specifically is my 20 interaction with her on October 4th where I then used 21 the Visual Analog Pain Scale to be able to compare 22 a rel -- you can do comparisons that way on severity.</p> <p>23 Q. So she -- when she saw you, she told you she 24 was experiencing severe dyspareunia; is that right?</p> <p>25 A. She graded her pain using the Visual Analog</p>
<p style="text-align: right;">Page 614</p> <p>1 to a woman going through menopause and the correlating 2 reduction in estrogen can cause dyspareunia. Do you 3 agree with that?</p> <p>4 MS. GAYLE: Objection. Form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. That's just what I stated. There would have 7 to be qualifiers on that. That's usually why we use the 8 Visual Analog Pain Scale to determine the severity and 9 the relative severity. She can have dryness. She can 10 have discomfort that is mild and usually treatable with 11 vaginal lubricants.</p> <p>12 Q. Did you read and consider Dr. Srock's, who is 13 the implanting physician in the case, her deposition 14 where she testified that Mrs. Wheeler has very thin 15 tissue and, in fact, an atrophic -- atrophic 16 endometrium? Did you consider that in reaching your 17 conclusion that the Avaulta products were the cause of 18 the dyspareunia?</p> <p>19 A. I would have to look at that specific record 20 with that. However, you said thinned endometrium. I 21 would expect that. She's a perimenopausal, 22 postmenopausal woman. You would expect the uterus to 23 be -- have a thinned endometrium. I can correlate it to 24 my exam on October 4th where I said the vagina was 25 well-estrogenized. So, in my experience, at a</p>	<p style="text-align: right;">Page 616</p> <p>1 Pain Scale, which is a validated study for patients to 2 be able to compare pain, on a scale of 1 to 10, with 1 3 being essentially nothing, 10 being the most severe pain 4 in life. She graded it at 8 during intercourse.</p> <p>5 Q. And did you consider the reliability of that 6 grading by Mrs. Wheeler when looking at her medical 7 records where she has reported only mild dyspareunia?</p> <p>8 A. Yeah. I am familiar with the records. We 9 probably want to talk -- go look specifically at those 10 notes, when that was, when was it relative to an 11 extrusion and a treatment of extrusion -- extrusion. Is 12 it possibly immediately after the extrusion? The pain 13 might have gone away and then comes back. And, 14 remember, this is also a progressive process.</p> <p>15 Klosterhalfen, et al., talks about 15 years' 16 progression. So what happened in the past is important, 17 but has to be looked at as the progression of the 18 disease process.</p> <p>19 Q. How about Mrs. Wheeler's preimplant complaints 20 of trouble with sexual intercourse, specifically burning 21 with sexual intercourse. Did you consider those reports 22 she made to her doctors in reaching your opinion that it 23 was the Bard's product only that has caused her problems 24 with sexual intercourse?</p> <p>25 MS. GAYLE: Objection. Form.</p>

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<p>1 BY THE WITNESS:</p> <p>2 A. Yeah. Number one, yes, I did consider those.</p> <p>3 Number two, as I stated earlier, as far as the quality</p> <p>4 and severity of the pain. Burning with sexual activity,</p> <p>5 I'm just trying to see if I have a Visual Analog Scale.</p> <p>6 I know I have here somewhere what it was before surgery</p> <p>7 and after surgery. It will be in my note somewhere.</p> <p>8 MS. GAYLE: Take your time, Doctor, and look for</p> <p>9 it.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Yeah. I only see in my notes, on quick</p> <p>12 review, a current Visual Analog Scale of 10 with sexual</p> <p>13 activity and a baseline of 6 to 7 constantly. I do not</p> <p>14 see where I state a preoperative Visual Analog Scale. I</p> <p>15 can go off of just what she said as far as advancement</p> <p>16 of the severity.</p> <p>17 Q. That's what she told you, correct?</p> <p>18 A. That's what she told me, yes.</p> <p>19 Q. Did you consider, Doctor, the reasons why</p> <p>20 Mrs. Wheeler's reports of the severity of dyspareunia</p> <p>21 may be different to you compared to her treating doctors</p> <p>22 as reflected in the records?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. Every time I interact with an individual I am</p>	<p style="text-align: right;">Page 617</p> <p>1 BY THE WITNESS:</p> <p>2 A. Absolutely I consider it, and that is a very</p> <p>3 important one. And I have to correlate it to my</p> <p>4 experience, my understanding of the medical literature,</p> <p>5 which, again, I have 509 papers that I've reviewed</p> <p>6 regarding this, including documentation on pain. I do</p> <p>7 know that from, again, Klosterhalfen, et al., mesh</p> <p>8 contraction is a progressive process.</p> <p>9 So if an individual has -- does not have pain,</p> <p>10 we have to look at exactly what's going on with that and</p> <p>11 if it progresses. Remember we had the paper yesterday</p> <p>12 where at one year they had 8 percent extrusion and at</p> <p>13 three years they had something like 19 percent, roughly.</p> <p>14 So things change.</p> <p>15 Q. You've mentioned Dr. Klosterhalfen quite a few</p> <p>16 times. Who is he?</p> <p>17 A. Klosterhalfen is a pathologist, Ph.D.,</p> <p>18 specializing in biomaterials. He is considered by some</p> <p>19 to be the king of meshes as far as understanding of</p> <p>20 meshes. And if you look at his CV, he has dozens and</p> <p>21 dozens of papers of looking at animal studies and human</p> <p>22 studies and mesh interaction from the vagina and also</p> <p>23 abdominal wall hernias.</p> <p>24 Q. Do you consider him to be a biomaterials</p> <p>25 expert?</p>
<p style="text-align: right;">Page 618</p> <p>1 always cognizant that people don't always tell the</p> <p>2 truth. You, as lawyers, know that, too. Anybody in the</p> <p>3 legal field knows it, the police force or otherwise. So</p> <p>4 that is always something I consider. All I can go off</p> <p>5 of is my personal interaction. I ask a question, I get</p> <p>6 a response, and then I correlate it to the physical</p> <p>7 exam.</p> <p>8 And when I do a physical exam, being aware of</p> <p>9 what we call malingering, I will try and do an exam,</p> <p>10 distract the patient, touch certain areas that I know</p> <p>11 would not be involved with meshes, ask them, Do you have</p> <p>12 pain here? If a patient is telling me they had pain</p> <p>13 everywhere I touch, inside the thigh, outside the thigh,</p> <p>14 I know that's not due to mesh. So all I can state is my</p> <p>15 questions and my physical exam correlate.</p> <p>16 Q. When you have a case like in any of these</p> <p>17 cases where you have medical records that reflect a much</p> <p>18 lesser degree of dyspareunia, do you consider that at</p> <p>19 all in reaching your opinions that the plaintiff</p> <p>20 experienced severe dyspareunia?</p> <p>21 If the medical record contradicts what she's</p> <p>22 telling you during your exam, do you consider that in</p> <p>23 reaching your conclusion with respect to severe</p> <p>24 dyspareunia?</p> <p>25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 620</p> <p>1 A. I consider him to be an advanced level</p> <p>2 individual who understands polymers and their</p> <p>3 interaction with the body.</p> <p>4 Q. So do you consider him to be a biomaterials</p> <p>5 expert?</p> <p>6 MS. GAYLE: Objection. Asked and answered.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Well, I just stated. He has -- he has extreme</p> <p>9 advanced knowledge arguably, the best in the world, in</p> <p>10 understanding meshes and their complications in animal</p> <p>11 and human, vaginal and transabdominal meshes.</p> <p>12 Q. Have you ever met with Dr. Klosterhalfen?</p> <p>13 A. No.</p> <p>14 Q. You read his report in this litigation?</p> <p>15 A. I've read --</p> <p>16 MS. GAYLE: Objection.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Yes. I've read his reports, but I've read</p> <p>19 more so his papers.</p> <p>20 Q. You understand he's an expert for the</p> <p>21 plaintiffs in this litigation as you are, correct?</p> <p>22 MS. GAYLE: Objection. Form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Yes. I do understand that, and I also put it</p> <p>25 in the mindset that I read his papers going back to the</p>

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<p style="text-align: right;">Page 621</p> <p>1 early '80s, which predate any of this. And what he 2 stated then and I correlate to what he states now to see 3 if it's changed.</p> <p>4 Q. In reaching your opinions in Mrs. Wheeler's 5 case about long-term quality-of-life issues and 6 inability to engage in sexual intercourse, did you 7 consider Mrs. Wheeler's attitudes or desires to have 8 sexual intercourse?</p> <p>9 A. I can't recall exactly what I spoke to her 10 about and her motivations as far as sexual activity. I 11 stated, you know, based upon my exam and what she stated 12 to me, that it's so severe she cannot have sexual 13 activity and it's a tremendous impact upon her quality 14 of life. So, yes, to answer your question, I did do 15 that.</p> <p>16 Q. Well, did you review or see, in any of the 17 medical records, Mrs. Wheeler's reports, that she 18 couldn't be bothered with sex because they were 19 experiencing marital problems?</p> <p>20 MS. GAYLE: Objection.</p> <p>21 BY MS. GEIST:</p> <p>22 Q. Did you see any of that?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. I would like to look at those records. The</p>	<p style="text-align: right;">Page 623</p> <p>1 MS. GAYLE: Objection, form. Mischaracterizes 2 evidence and testimony in this case.</p> <p>3 BY THE WITNESS:</p> <p>4 A. You're taking a certain -- I would like to see 5 those records, which would probably be important. Let's 6 see what the context and when it is occurring. However, 7 on my interaction with her on October 4th, 2014, what 8 she stated to me, which correlates to my physical exam, 9 is the impact upon her quality of life has been 10 tremendous and cannot engage in any -- cannot. Not that 11 she doesn't choose. She cannot engage in significant -- 12 excuse me, engage in any meaningful -- cannot engage in 13 any meaningful sexual activity and has lost that 14 intimacy.</p> <p>15 Q. Well, I understand that's what she told you, 16 Dr. Elliott. Would Mrs. Wheeler, as a plaintiff in this 17 litigation, tell you anything other than that in order 18 to move her case forward?</p> <p>19 MS. GAYLE: Objection. Move to strike. Also, 20 objection. It mischaracterizes testimony and 21 argumentative.</p> <p>22 BY THE WITNESS:</p> <p>23 A. I cannot state what -- what Mrs. Wheeler and 24 her various different motivations are. All I can do is 25 I ask questions keeping an open mind, keeping the</p>
<p style="text-align: right;">Page 622</p> <p>1 fact that she might not want to be bothered by sexual 2 activity is understandable. But then if she were to 3 change her mind and not be able to, that is an important 4 issue.</p> <p>5 Q. Well --</p> <p>6 A. She should have the right to be able to have 7 sexual activity if she chooses to.</p> <p>8 Q. If she has marital problems and she doesn't 9 want to be bothered with sex, obviously, she wouldn't 10 have any long-term quality-of-life impact, true?</p> <p>11 MS. GAYLE: Object to form. Mischaracterizes 12 Ms. Wheeler's testimony and her husband's testimony.</p> <p>13 BY THE WITNESS:</p> <p>14 A. I'm of the opinion the woman should have the 15 right to choose what she wants to do with her body. If 16 she is having marital discourse or whatever type of 17 discourse and does not want to partake in sex, that's 18 fine. But if she were to change her mind, she has the 19 right to be able to do that.</p> <p>20 Q. And I don't disagree with you. But my 21 question only is this, if she's indicated in her medical 22 records, maybe not to you, that she couldn't be bothered 23 with sex, then obviously she doesn't have any long-term, 24 quality-of-life issue if she's not interested in 25 engaging in sex? Would you agree with me on that?</p>	<p style="text-align: right;">Page 624</p> <p>1 concept of malingering very well present, correlate it 2 to what my physical exam is. And my physical exam 3 demonstrated a severely scarred and painful vagina, 4 which is not consistent remotely with meaningful sexual 5 activity.</p> <p>6 Q. Well, I guess what I'm asking you, Doctor, is 7 this, when Mrs. Wheeler reported to you that she's 8 experiencing severe dyspareunia, did you go back and 9 look at her records and see if that report correlated to 10 what she was telling her treating doctors over the 11 years?</p> <p>12 A. Well, by all means. I mean, I've read the 13 records. But, again, what happened then versus now was 14 that, you know, was it when she was having mesh 15 extrusion and she wants nothing to do with sexual 16 activity? We have to figure out what is exactly going 17 on. You're taking one -- one line from somewhere and 18 I'm taking, when I examined her and when I personally 19 spoke with her, what she said.</p> <p>20 Q. Now, moving to the paragraph regarding the 21 lack of physical intimacy and the long-term outcome of 22 impact on quality-of-life issues leading to the 23 possibility of depression and the suicide, that's the 24 same paragraph you have for Mrs. Alonso and Mrs. Wheeler 25 and Mrs. Bolyard, correct?</p>

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<p style="text-align: right;">Page 625</p> <p>1 A. That is correct.</p> <p>2 Q. Okay. So are you giving an opinion in this 3 case that Mrs. Wheeler will experience depression or 4 commit suicide as a result of the problems that she 5 contends she is experiencing?</p> <p>6 A. I stated the same statement as in my previous 7 testimony with Alonso, that, based upon the data out 8 there in multiple different manuscripts, my review of 9 the literature, my daily interaction with female 10 patients, that the loss of intimacy, the isolation, the 11 embarrassment, the guilt, the perception of inability 12 to, for lack of a better phrase, satisfy their partner, 13 that can lead to depression and all of the emotions we 14 discuss -- discussed.</p> <p>15 Q. It's fair to say it would be speculation to 16 opine, in any of these three cases, that any of these 17 women will experience depression as a result of the 18 complications they say they've had from the mesh?</p> <p>19 MS. GAYLE: Objection. Form.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. It would be speculation to say Mrs. Alonso or 22 Mrs. Wheeler or Mrs. Bolyard will experience depression 23 based on the complications that they say they've had 24 from the Bard mesh?</p> <p>25 MS. GAYLE: Objection. Form. Mischaracterizes</p>	<p style="text-align: right;">Page 627</p> <p>1 Bard implant surgery?</p> <p>2 A. Absolutely. And that's all the more worrisome 3 in an individual with underlying baseline depression.</p> <p>4 Now you have added on another stressor like chronic pain 5 and then more isolation and more loneliness. So, yes, 6 that is further evidence or worrisome that, you know, 7 this is a major, serious tragic problem for these 8 individuals.</p> <p>9 Q. Would you agree with me that Mrs. Wheeler 10 could have still experienced depression and would still 11 be a user of antidepressants if she never even had the 12 Bard implant surgery?</p> <p>13 A. Depression is, unfortunately, frequently not a 14 curable problem; and, if you add in more stressors, it 15 makes it worse. So, yes, by all means, depression was 16 there. That means, again, the more importance of the 17 added stress of the pain.</p> <p>18 Q. Well, you would agree with me, Doctor, that 19 you can't say in this circumstance that, if Mrs. Wheeler 20 continues to experience depression, that it's all due to 21 the problems she says she's had from the Bard surgery -- 22 from the Bard implant surgery? Pardon me.</p> <p>23 A. That's -- well, again, my report states what 24 it states. I am not stating that Bard product caused 25 her original depression. I am saying that -- and I</p>
<p style="text-align: right;">Page 626</p> <p>1 testimony and his report. The report speaks for itself.</p> <p>2 BY THE WITNESS:</p> <p>3 A. Yeah. My report, the words that I wrote down 4 here, I chose very carefully. I did not state it will 5 lead to. The symptoms that she is experiencing, based 6 upon my experience, review of the literature, can lead 7 to these feelings of isolation, loneliness, depression, 8 and, unfortunately, suicide.</p> <p>9 Q. Well, would you agree with me, Doctor, that 10 the use of the term suicide is a pretty highly charged 11 term? It's a pretty serious term to throw in there in 12 this report?</p> <p>13 A. The data backs it up, though. Look, I had two 14 quotes there, two papers. And so, yeah, chronic pain, 15 loss of intimacy, loneliness, depression, I don't think 16 there is anybody going to challenge that depression and 17 suicide correlate. I'm not saying they will have it.</p> <p>18 I'm saying that these are things that can, in the very 19 severe situations, lead to that.</p> <p>20 Q. How about in Mrs. Wheeler's specific case? 21 Did you consider, in reaching your opinions, that the 22 quality of life issues that you say were caused by the 23 Bard Avaulta products may cause her depression? Did you 24 consider, in reaching those opinions, that she had been 25 using antidepressants for a number of years prior to the</p>	<p style="text-align: right;">Page 628</p> <p>1 don't think there is anybody who is going to be 2 questioning this -- that added stress, pain, loneliness, 3 lack of intimacy can worsen the condition.</p> <p>4 Q. I assume you would agree with me, Doctor, that 5 you're not an expert in psychiatry or psychology, true?</p> <p>6 A. I am not trained in psychology or psychiatry.</p> <p>7 Q. So you're not an expert in either of those 8 fields, correct? You wouldn't hold yourself out as an 9 expert in the fields of psychiatry or psychology or 10 mental health, in general?</p> <p>11 A. No. Those, I think every physician deals with 12 individuals dealing with major issues. To a certain 13 extent, every physician, especially if they deal with 14 pain, has to be aware and recognize these and also aware 15 and recognize their limitations to ask certain questions 16 and get the individual to somebody with advanced 17 training.</p> <p>18 Q. Doctor, I'm asking if you recognize your 19 limitations. Are you putting yourself out there as an 20 expert in psychiatry, psychology, and mental health 21 disorders?</p> <p>22 MS. GAYLE: Object to form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. Well, no. I think I answered that. No, I am 25 not a psychiatrist or a psychologist, but I deal with a</p>

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<p style="text-align: right;">Page 629</p> <p>1 large number of women who suffer from depression and 2 things, but I do not hold myself out as being an expert 3 in psychology or psychiatry. I do not hold an advanced 4 degree in that area.</p> <p>5 Q. Okay. Thank you. Did you see, in your review 6 of Mrs. Wheeler's records, that she experienced a 7 dehiscence in weeks postop?</p> <p>8 A. Yeah. Her surgery was on July 7th, 2008. And 9 on August 26th -- August 26th is when it was clear. 10 But, though, if you go back to July 22nd, I think we 11 start to see the beginnings of the dehiscence, that it 12 manifested itself on August 26th.</p> <p>13 Q. And just so the jury understands, a dehiscence 14 is what?</p> <p>15 A. It's a separation of a wound, poor healing.</p> <p>16 Q. It's sort of a wound rupture at the suture 17 site; is that correct?</p> <p>18 A. Yeah. Well, dehiscence technically just means 19 a separation. In a surgical setting, it is implied that 20 that is the incision that opens.</p> <p>21 Q. And, in this case, the separation we're 22 talking about is the vaginal wall, correct?</p> <p>23 A. The -- correct. The anterior, 4-millimeter 24 mesh extrusion on August 26th. So it is just the 25 anterior component. According to Dr. Sprock's note,</p>	<p style="text-align: right;">Page 631</p> <p>1 A. No. The surgery was July 7th. July 22nd she 2 was examined. The tissue was turned a little yellowish. 3 Now, Dr. Sprock says it's part of the healing process. 4 What I'm saying is, in hindsight -- I don't disagree 5 with Dr. Sprock at that moment; but, in hindsight, that 6 was probably the start of impaired healing.</p> <p>7 Q. So two weeks out from the surgery, the 8 dehiscence had started, correct?</p> <p>9 A. No. I'm saying, if we want to go purely off 10 of the record, Dr. Sprock states it's part of the 11 healing process. So she was there. She laid eyes on 12 the individual. I did not. So if we go off of her 13 record, she's saying this is normal healing. So then 14 the 26th, clear-cut that there is impaired healing and 15 the dehiscence.</p> <p>16 Q. Now, Dr. Sprock did not repair the dehiscence 17 when she made that diagnosis in her patient, 18 Mrs. Wheeler, correct?</p> <p>19 A. No. It says, on the August 26th office visit, 20 she noticed an anterior 4-millimeter mesh extrusion. 21 Mesh is our word we put in there. Dr. Sprock trimmed 22 the extrusion and sutured the site closed. So she did 23 repair it.</p> <p>24 Q. Did you review the record for Mrs. Wheeler on 25 September 23rd, 2008, when wound dehiscence was noted as</p>
<p style="text-align: right;">Page 630</p> <p>1 there was -- well, actually, I have nothing down here 2 pertaining to posterior. So it was just anterior.</p> <p>3 Q. The dehiscence or the separation of the 4 vaginal wall would cause the exposure of the mesh, 5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. And what are some of the known causes of 8 dehiscence in the first instance?</p> <p>9 A. Implantation of mesh, surgery, wound 10 infection. You know, those are probably the top things 11 that come to my mind.</p> <p>12 Q. Is surgical error one of the known causes for 13 wound dehiscence?</p> <p>14 A. Not eight weeks out, ten weeks out.</p> <p>15 Immediately after surgery, if a wound breaks open, and 16 I'd be willing to go on -- obviously, I am on the 17 record. If a wound breaks open a day or two after 18 surgery, unless you have a hematoma, that would probably 19 be poor surgical technique.</p> <p>20 Q. Well --</p> <p>21 A. Closing at ten weeks afterwards, then you 22 start talking about poor healing.</p> <p>23 Q. Well, you actually corrected me and you said 24 the dehiscence started earlier, that it started in July 25 of 2008?</p>	<p style="text-align: right;">Page 632</p> <p>1 well as the extrusion and it was also noted that the 2 patient does not desire surgical suturing?</p> <p>3 A. Yeah. Again, I have that note down here from 4 the 23rd. I would have to review the exact records. 5 But, according to my note -- oh, excuse me. You're 6 correct. You said September 23rd, patient aware of 7 dehiscence, not bothered with intercourse, and left it. 8 But then it was then repaired on October 10th. But you 9 are correct, on the September 23rd, no repair was done. 10 Q. So you think the October which date now? 11 A. September 23rd, 2008, eight-week visit, 12 Dr. Sprock again noticed vaginal mesh extrusion. 13 According to my notes, and we can correlate that with 14 the records, at that point in time, no treatment was 15 done. However, on October 10th, so, roughly, what, 16 two -- two and a half weeks later, Ms. Wheeler returned, 17 the mesh extrusion was, again, noted and then it was cut 18 and they continued conservative therapy from then. 19 Q. Now, the October 10th, 2008 record notes the 20 extrusion, as you've just said, and that the extrusion 21 was cut or there was an excision done? 22 A. Correct. 23 Q. Is there any record that notes that the 24 dehiscence was repaired? 25 A. Well, no. They -- you wouldn't necessarily be</p>

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<p style="text-align: right;">Page 633</p> <p>1 suturing that up at that point in time.</p> <p>2 Q. Why not?</p> <p>3 A. Because it won't heal. It's infected. It's</p> <p>4 contaminated tissue. If you close it over, you're more</p> <p>5 likely to create an abscess. So the standard treatment</p> <p>6 that far out would be just to excise the mesh. Get rid</p> <p>7 of the foreign body back as far as you can with the hope</p> <p>8 the tissue is going to granulate in.</p> <p>9 Q. So is it your opinion that it was within the</p> <p>10 standard of care not to repair the wound dehiscence?</p> <p>11 A. I -- on which day are we talking about,</p> <p>12 October 10th?</p> <p>13 Q. Right.</p> <p>14 A. Okay.</p> <p>15 Q. Is that the ten-week follow-up postop visit?</p> <p>16 A. That is ten-and-a-half-week follow-up, yes.</p> <p>17 The ten and a half weeks out I would not have closed a</p> <p>18 mesh extrusion. I would have trimmed the mesh either in</p> <p>19 the clinic setting or in the operating room, but I would</p> <p>20 not have closed the wound.</p> <p>21 Q. If Mrs. Wheeler had engaged in sexual activity</p> <p>22 after that time, could that have led to some</p> <p>23 complications relating to the mesh due to the wound</p> <p>24 dehiscence?</p> <p>25 MS. GAYLE: Objection. Form.</p>	<p style="text-align: right;">Page 635</p> <p>1 advise a woman to refrain from engaging in sexual</p> <p>2 intercourse when she has a vaginal wound dehiscence?</p> <p>3 A. Well, at 26 -- August 26th, it's a</p> <p>4 4-millimeter mesh extrusion, okay, which is, what, not</p> <p>5 even a quarter of an inch. Maybe less than that. Let</p> <p>6 me just find out what that would be at. 4 millimeters</p> <p>7 is, at the most, a quarter of an inch. Dr. Srock did</p> <p>8 the appropriate thing. She closed it, trimmed the mesh,</p> <p>9 and then closed it. And I don't know when she started</p> <p>10 sexual activity. But -- again, there's certain gaps</p> <p>11 here. I think we have to look at the deposition and</p> <p>12 talk to Dr. Srock and the patient.</p> <p>13 Q. Sitting here today, you can't tell me one way</p> <p>14 or the other whether it would be within the standard of</p> <p>15 care to instruct a woman experiencing vaginal wound</p> <p>16 dehiscence to avoid sexual intercourse?</p> <p>17 MS. GAYLE: Objection. Form.</p> <p>18 BY THE WITNESS:</p> <p>19 A. Well, I think that's actually a very good</p> <p>20 thing for the IFU to help out the physician. I don't</p> <p>21 know of a standard out there with meshes of what to do.</p> <p>22 I don't know of any paper out there. If a company has</p> <p>23 information that, if there is a wound dehiscence and</p> <p>24 delayed healing, completely avoid anything per vagina</p> <p>25 would actually be very helpful. That would be an</p>
<p style="text-align: right;">Page 634</p> <p>1 BY THE WITNESS:</p> <p>2 A. After October 10th?</p> <p>3 Q. Yes.</p> <p>4 A. Well, I don't know. I would have to see the</p> <p>5 record as far as if there are warnings about not</p> <p>6 becoming sexually active, but I can't speak to that.</p> <p>7 Q. Well, if there's no warnings in the records</p> <p>8 for Mrs. Wheeler about not becoming sexually active, is</p> <p>9 it your opinion that she should have been told not to</p> <p>10 become sexually active with a wound dehiscence?</p> <p>11 MS. GAYLE: Objection. Form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Well, I would have to look at -- I just say,</p> <p>14 in my notes, going off Dr. Srock's note, it says a mesh</p> <p>15 extrusion was noted. I don't have the dimensions of</p> <p>16 that extrusion. If the extrusion were large</p> <p>17 centimeters, then I think abstaining from sexual</p> <p>18 activity is appropriate.</p> <p>19 If it's just the prongs poking through and</p> <p>20 it's a minimal deal, then there's probably minimal</p> <p>21 warning that needs to be given to the patient. So,</p> <p>22 again, I don't know -- or, unfortunately, our notes are</p> <p>23 not clear as far as the degree of extrusion.</p> <p>24 Q. Well, what about the wound dehiscence,</p> <p>25 specifically? Isn't it standard of care to instruct or</p>	<p style="text-align: right;">Page 636</p> <p>1 instruction that probably could have helped Dr. Srock</p> <p>2 if you feel that she did something inappropriate. I</p> <p>3 don't -- again, I don't know. I can't say. I can't</p> <p>4 throw fault here.</p> <p>5 Q. You don't have an opinion one way or the</p> <p>6 other; is that fair to say?</p> <p>7 MS. GAYLE: Objection, form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Well, no. I did say. I said that she,</p> <p>10 Dr. Srock, is the one who we say laid eyes on the</p> <p>11 patient, did the exam. I don't know what warnings she</p> <p>12 gave. So there is nothing clear in the literature.</p> <p>13 There is nothing in the IFU to say, Hey, if you've got a</p> <p>14 complication, be careful with this.</p> <p>15 Q. Did -- in reaching your opinions in</p> <p>16 Mrs. Wheeler's case that the mesh was the cause or is</p> <p>17 the cause of her reported symptoms, did you consider</p> <p>18 surgical technique?</p> <p>19 A. Oh, I -- I'm sorry. Absolutely. Every time I</p> <p>20 review a patient, as I've stated previously with Alonso,</p> <p>21 we're looking at the totality of that patient, their</p> <p>22 medical records, their past medical history, all of the</p> <p>23 diagnoses, the surgical implementation, the management</p> <p>24 of this patient after surgery.</p> <p>25 Q. Did you consider whether Dr. Srock implanted</p>

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<p style="text-align: right;">Page 637</p> <p>1 the mesh too tight and not tension-free on July 7th, 2 2008?</p> <p>3 MS. GAYLE: Objection. Form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. I would have to go back to the operative note 6 to go over that specifically, which I don't have. In 7 reading the notes, on all of the individuals today, I 8 cannot point to something that I could say would be a 9 medical error or malpractice. It would all have been 10 within acceptable surgical standards.</p> <p>11 Q. Did you read the testimony from Dr. Zipper in 12 Mrs. Wheeler's case?</p> <p>13 A. Yeah. Dr. Zipper? Yes. Yes. Dr. Zipper is 14 in her -- I believe in Dr. Srock's group, former group. 15 And according to my recollection -- and I could be 16 wrong. We could pull out that actual deposition -- he 17 stated that she did not do anything surgically 18 incorrect.</p> <p>19 Q. Do you recall Dr. Zipper testifying that, when 20 he examined Mrs. Wheeler, that the mesh arms were too 21 tight and that this was possibly contributing to her 22 dyspareunia?</p> <p>23 A. I do not recall that specific deposition. We 24 can look at it. However, I would agree completely with 25 that diagnosis. These mesh arms, as I've stated, are</p>	<p style="text-align: right;">Page 639</p> <p>1 A. That is correct. 2 Q. The language that I pointed you to earlier on 3 the IFU for the Avaulta Plus product where it says that 4 the mesh should be implanted tension-free, that's the 5 same language in the Avaulta Solo IFU; is it not?</p> <p>6 A. My recollection, we'd have to compare them 7 side by side, as they are essentially the same document. 8 But I would not agree with you as far as it being 9 tension-free. They mentioned twice avoid excessive 10 tension, without excessive tension.</p> <p>11 Q. Now, we looked at the operative note in 12 Mrs. Alonso's case, correct?</p> <p>13 A. That is correct. 14 Q. And you would agree with me that, when we 15 looked at that operative note, that medical record, 16 nowhere in it did it indicate that the mesh was placed 17 tension-free?</p> <p>18 A. No. But I would say it is stated it avoided 19 excessive pressure. He said apply positive pressure 20 against the posterior bladder. That, to me, is not 21 excessive tension.</p> <p>22 Q. But it doesn't say, I avoided excess tension 23 or I placed the mesh tension-free? It doesn't say that 24 in the operative report for Mrs. Alonso, does it?</p> <p>25 MS. GAYLE: Objection. Form. He's asked and</p>
<p style="text-align: right;">Page 638</p> <p>1 high-density, small pore. They contract over time. So, 2 by all means, they're tight. Based upon my exam on 3 October 4th, I felt that knot -- I forget which side -- 4 extremely painful in the obturator foramen. So I agree. 5 They are too tight.</p> <p>6 Q. But did you consider the possibility that the 7 arms of the mesh were too tight because Dr. Srock's 8 surgical technique was not according to the IFU as we 9 looked at earlier together?</p> <p>10 A. We would have to pull out the actual operative 11 note. From my recollection, from all individuals, that 12 this is put in loose with avoiding excessive tension as 13 what the IFU specifically states. I do not recall 14 anything, from this operative note, stating anything 15 about it being excessively tight.</p> <p>16 MS. GAYLE: And, just for the record, Elliot 30 is 17 the Avaulta Plus IFU, and this is an Avaulta Solo 18 product, and your question referenced the IFU that we 19 looked at earlier, which is the Plus.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. Point well taken by counsel. But, Doctor, you 22 looked at the IFUs for the Plus product and the Solo 23 product, correct --</p> <p>24 A. That is correct.</p> <p>25 Q. -- on your reliance list?</p>	<p style="text-align: right;">Page 640</p> <p>1 answered that question previously, and I thought we were 2 on to Wheeler.</p> <p>3 BY THE WITNESS:</p> <p>4 A. He does not use those exact words; however, I 5 do feel he is following the specific words of the IFU 6 saying avoid excessive tension. He is avoiding 7 excessive tension, so he is following the IFU.</p> <p>8 Q. That's your interpretation of the report in 9 Mrs. Alonso's case?</p> <p>10 A. As a surgeon who takes care of these with a 11 large amount of experience, yes. He is following -- 12 this is not just an opinion. He is following the 13 avoiding excessive tension, which is mentioned twice in 14 the IFU.</p> <p>15 Q. And what about Dr. Srock? Did Dr. Srock 16 similarly avoid implanting the Avaulta Solo products in 17 Mrs. Wheeler?</p> <p>18 A. I would have to see that operative note.</p> <p>19 Q. You don't remember one way or the other 20 sitting here today?</p> <p>21 A. I read a lot of operative notes and I'd want 22 to -- because this is very important to know the tension 23 of this. I would want to see the exact operative note.</p> <p>24 MS. GEIST: Can we go off the record one minute?</p> <p>25 VIDEO TECHNICIAN: We're off the record. The time</p>

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<p>1 is 12:59 p.m. 2 (A short recess was had.) 3 VIDEO TECHNICIAN: We're back on the record. The 4 time is 1:01 p.m. 5 BY MS. GEIST: 6 Q. Dr. Elliott, as you requested, you wanted to 7 see the operative note for Mrs. Wheeler, Mrs. Wheeler's 8 procedure? 9 A. Correct. 10 Q. So that was in the materials you had reviewed 11 in forming your opinions about Mrs. Wheeler's case, 12 correct? 13 A. Yes. 14 MS. GEIST: I think I'm up to Exhibit 32. 15 THE REPORTER: 34. 16 (Elliott Deposition Exhibit No. 34 17 was marked for identification.) 18 BY MS. GEIST: 19 Q. 34, thank you. Doctor, let me hand you what 20 we've marked as Exhibit 34. I apologize for the fact 21 that it doesn't have staples. 22 MS. GAYLE: I'm going to take care of that for you, 23 Counsel. 24 MS. GEIST: Thank you, ma'am. 25 MS. GAYLE: I travel with a stapler.</p>	<p style="text-align: right;">Page 641</p> <p>1 (Record read as requested.) 2 BY THE WITNESS: 3 A. It states here, tensed with an 8 Hegar 4 dilator. So that means an 8 Hegar dilator was able to 5 be inserted between the mesh. So that means it was 6 placed loosely. 7 Q. And you are referring to page 2 of the 8 operative report, which we just marked as Exhibit 34? 9 A. That's correct, on Ms. Wheeler. 10 Q. And this is the second paragraph, 11 second-to-the-last sentence of that paragraph? 12 A. Correct. 13 Q. And that's the basis for your opinion that 14 Dr. Srock implanted the mesh tension-free, that 15 sentence that says tensed with an 8 -- 16 A. Hegar dilator. 17 Q. -- Hegar dilator? 18 MS. GAYLE: Objection. Form. 19 BY THE WITNESS: 20 A. Well, that's -- 21 Q. That's my question. 22 A. That's what that means. That means you can 23 fit an 8 Hegar dilator between the mesh and the tissues. 24 Q. So that's the basis of your opinion, that the 25 mesh was implanted tension-free by Dr. Srock?</p>
<p>1 MS. GEIST: Thank you, ma'am. I used to. I should 2 bring that again. 3 BY MS. GEIST: 4 Q. I should have just marked the records in the 5 entirety, but let's just isolate the operative report 6 for Mrs. Wheeler. And this is dated July 7, 2008. Do 7 you see that, Doctor? 8 A. Correct. 9 Q. And this is the operative report from 10 Dr. Srock. And you looked at this in the past, I 11 assume, in order to inform your opinions in the case? 12 A. That is correct. 13 Q. Okay. Could you tell, from reviewing the 14 operative report, whether the implanting surgeon did, in 15 fact, place the mesh tension-free? 16 MS. GAYLE: Objection. Give him just one moment, 17 Counsel, to review this three-page document. 18 BY MS. GEIST: 19 Q. There's actually nothing on the third page. 20 But, Doctor, you can take as much time as you want. 21 MS. GAYLE: Sorry. 22 BY THE WITNESS: 23 A. Okay. I'm done -- I'm done with it. What was 24 your question again? 25 MS. GEIST: Can you read back my question, please?</p>	<p style="text-align: right;">Page 642</p> <p>1 MS. GAYLE: Objection. Form. 2 BY THE WITNESS: 3 A. Well, that's what - that's what Dr. Srock 4 states right here. 5 Q. I understand that. But is that the basis for 6 your opinion that Dr. Srock implanted the mesh 7 tension-free, that sentence? 8 MS. GAYLE: Same objection. 9 BY THE WITNESS: 10 A. Yes. That's the basis for my opinion. 11 Q. Okay. Thank you. You can set that aside, 12 Doctor. 13 Do you recall, from your review of the records 14 in this case, that Dr. Zipper described the mesh as 15 being rolled up when that doctor performed an excision 16 about four years after the implant? 17 A. Yeah. I recall that terminology. And it also 18 should be noted that Dr. Srock tacked the mesh anterior 19 and posterior, so following the IFU instructions. 20 Q. If the mesh had been implanted flat and 21 without tension at the time of the initial surgery, 22 would it have been possible to see rolling four years 23 later due to tissue, due to tissue ingrowth? 24 MS. GAYLE: Object to form. 25 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 645</p> <p>1 A. Absolutely. That's mesh contraction. That's what I see on a daily basis.</p> <p>3 Q. But, Doctor, would you agree with me that, 4 once tissue ingrowth occurs, you are less likely to see 5 erosion for the logical reason that the mesh has ingrown 6 or combined with the woman's tissue; isn't that true?</p> <p>7 MS. GAYLE: Objection to form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. No, it's absolutely wrong.</p> <p>10 Q. Why?</p> <p>11 A. That's why we see mesh extrusion years after the implantation and it's a progressive process. As the mesh contracts up to 80 percent, based upon certain studies, there is rolling, folding, uneven pressure on the tissues, especially with the arms. There's uneven pulling on the vagina and extrusion happens because of pressure, poor healing, degradation of the product.</p> <p>18 Q. What -- what's the basis for your opinion that we see 80 percent of mesh contraction?</p> <p>20 MS. GAYLE: Objection. Form. I'm sorry. I believe that was a yesterday opinion, but I may have missed it. Did he just mention 80 percent? Madam Court Reporter, can you read back his answer? I'm so sorry, Madam Court Reporter.</p> <p>25</p>	<p style="text-align: right;">Page 647</p> <p>1 80 percent, I was -- I actually underestimated. It says 2 85 percent here.</p> <p>3 Q. And was that study an animal study or a study 4 of -- looking at mesh in women?</p> <p>5 A. Pelvic mesh volumes using translabial ultrasonography that's in females, humans.</p> <p>7 Q. And we talked yesterday -- and I don't want to 8 repeat it, but just to confirm -- you had not considered 9 the Dietz study in reaching your opinions about mesh 10 contraction, correct?</p> <p>11 MS. GAYLE: Objection to form. And that is exactly 12 correct, Counsel. It was discussed yesterday. So I'm 13 going to instruct him not to answer that.</p> <p>14 MS. GEIST: That's fine. He answered it yesterday.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. Okay. Doctor, with respect to the opinions in 17 your report, excuse me, from Mrs. Wheeler that go to the 18 risks that you contend Bard should have included in the 19 IFU and did not?</p> <p>20 A. Correct.</p> <p>21 Q. That's -- I just want to make sure that we're 22 clear on the record. That's the same list, 23 two-and-a-half page list, that you had in Mrs. Alonso's 24 report, correct?</p> <p>25 A. It should be the same, yes.</p>
<p style="text-align: right;">Page 646</p> <p>1 (Record read as requested.)</p> <p>2 MS. GAYLE: Excuse me, Counsel. My apologies.</p> <p>3 Thank you.</p> <p>4 MS. GEIST: No problem.</p> <p>5 MS. GAYLE: Please, continue.</p> <p>6 BY THE WITNESS:</p> <p>7 A. Okay. Now, what was your question then?</p> <p>8 Q. I just want to know what studies are you 9 relying on in support of your opinion that we see mesh 10 contraction up to 80 percent?</p> <p>11 A. I'm relying upon -- I'm going to have to pull 12 out my expert report from yesterday, the general 13 specific. And the section on mesh contraction, I can go 14 through the studies and list them for you.</p> <p>15 Q. I just want to know the 80 percent one, 16 Doctor?</p> <p>17 A. Okay. Letouzey, this is on page 19 of my 18 expert report, Letouzey, L-E-T-O-U-Z-E-Y, which I 19 mentioned earlier today, reviewed the long-term 20 placement of mesh, pelvic mesh volumes over time using 21 three-dimensional, translabial ultrasound and found 22 contraction of 30 percent, 65 percent, 85 percent at a 23 follow-up duration of three, six, and eight years.</p> <p>24 Correlating this with Bard's own internal documents that 25 showed a substantial risk of up to 50 percent. But my</p>	<p style="text-align: right;">Page 648</p> <p>1 Q. And it's the same list that you have in 2 Mrs. Bolyard's report?</p> <p>3 A. That is correct.</p> <p>4 Q. And would you agree with me, Dr. Elliott, that 5 you can't state, to a reasonable degree of medical 6 certainty or probability, that had all of this 7 information been included by Bard in the IFU for the 8 Avaulta Solo product, that this information would have 9 been conveyed to Mrs. Wheeler by her implanting doctor?</p> <p>10 MS. GAYLE: Objection. Form.</p> <p>11 BY THE WITNESS:</p> <p>12 A. You're forcing me to speculate what another 13 individual would have done.</p> <p>14 Q. No, no, no. I'm not. I'm asking you not to. 15 I'm asking you to agree with me that you can't say, 16 sitting here today, that had Bard put all of this 17 information in the IFU that you say Bard should have 18 done because Bard knew about all of these risks and 19 didn't communicate them to doctors, if Bard had done 20 what you say Bard should have done, that that 21 information would have been relayed to Mrs. Wheeler?</p> <p>22 MS. GAYLE: Objection. Form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. It should be the decision and moral obligation 25 of the implanting surgeon to have all information</p>

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<p style="text-align: right;">Page 649</p> <p>1 available. A reasonable surgeon and doctor would relay 2 that information on to the patient. I cannot speculate 3 what this hypothetical individual would have done had 4 they had this information.</p> <p>5 Q. Well, we're not talking about a hypothetical 6 individual. We're talking about Dr. Srock in 7 Mrs. Wheeler's case. So that's my question. You 8 can't -- you're not going to sit here and say that your 9 opinion is had Bard provided all of this information to 10 Dr. Srock in the IFU for the Avaulta Solo product, that 11 that information would have been relayed by the doctor 12 to his patient, Mrs. Wheeler. You can't say that, 13 correct?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. I can state exactly how I stated with Alonso 17 and exactly what I'll state with Bolyard, and that I can 18 state that a reasonable surgeon would relay that 19 information on. I would do it and do it in my practice 20 of all known potential complications.</p> <p>21 Q. And you have no way of saying, because it 22 would be pure speculation, to use your own words, what 23 would have happened in the case of Mrs. Alonso, 24 Mrs. Wheeler, and Mrs. Bolyard, correct?</p> <p>25 A. Well, you're asking me to speculate. I can't</p>	<p style="text-align: right;">Page 651</p> <p>1 A. Yeah, you did. You said native repair and 2 anterior sacrocolpopexy.</p> <p>3 Q. No. I asked you about -- well, I don't want 4 to argue it.</p> <p>5 A. You said same complications.</p> <p>6 Q. No. I said pain and dyspareunia. So let me 7 make sure you understand my question, because that's 8 always important in these depositions.</p> <p>9 I'm asking you about her complaints of pain 10 and dyspareunia. And my question is this, had she had a 11 native tissue repair or an abdominal sacrocolpopexy, 12 instead of a transvaginal mesh procedure, could she 13 still have experienced pain and dyspareunia after either 14 one of those other procedures?</p> <p>15 MS. GAYLE: Objection. Form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Not in my practice, my experience, at a 18 high-volume tertiary care center, taking care of 19 patients on a daily basis. I have never seen a native 20 repair or an abdominal sacrocolpopexy or robotic 21 sacrocolpopexy with the severity of pain and the 22 location of the pain and the delayed onset of pain like 23 I've seen with pelvic meshes. The same answer I gave 24 with Alonso and the same one I'll give with Bolyard.</p> <p>25 Q. All right. So just so I understand your</p>
<p style="text-align: right;">Page 650</p> <p>1 speculate. I would -- I am of the opinion a patient has 2 the right to have that information available to her for 3 her own body to make her own choice.</p> <p>4 Q. Had Mrs. Wheeler had a native tissue repair or 5 an abdominal sacrocolpopexy procedure, would you agree 6 with me that she could have experienced the same issues 7 and complications she's complaining about now in her 8 complaint?</p> <p>9 MS. GAYLE: Objection. Form. Assumes -- also, 10 objection, assumes facts not in evidence.</p> <p>11 BY THE WITNESS:</p> <p>12 A. I disagree.</p> <p>13 Q. You disagree?</p> <p>14 A. (No verbal response.)</p> <p>15 Q. So let me explore that. So if Mrs. Wheeler 16 had a native tissue repair for her anterior and 17 posterior defects, you don't agree that she could have 18 experienced pelvic pain and dyspareunia after that 19 procedure?</p> <p>20 A. Same answers that we went down before with the 21 first one, Alonso, applies here. Number one, 22 Ms. Wheeler would never have had a mesh extrusion. If 23 you had a native repair, it's impossible. It's not 24 going to happen.</p> <p>25 Q. Right. That's why I didn't ask you about it.</p>	<p style="text-align: right;">Page 652</p> <p>1 answer, so Mrs. Wheeler still could have experienced 2 pelvic pain and dyspareunia. But, in your opinion, it 3 would not have been to the same degree as she's 4 experiencing per her testimony today, correct?</p> <p>5 MS. GAYLE: Object -- objection to form and 6 objection, mischaracterizes his testimony.</p> <p>7 BY THE WITNESS:</p> <p>8 A. It's not just my opinion. The literature 9 supports it. And I forget what the second part is after 10 the objection. I'll be quiet then because I can't 11 recall what the last part of it was.</p> <p>12 Q. So let me ask my question again. You don't 13 disagree with me, do you, Dr. Elliott, that Mrs. Wheeler 14 could have experienced pelvic pain and dyspareunia after 15 having a native tissue or an ASC procedure?</p> <p>16 MS. GAYLE: Objection. Asked and answered.</p> <p>17 BY THE WITNESS:</p> <p>18 A. Again, with the qualifiers of the severity, 19 the frequency, the location, and the delayed onset and 20 the permanency and the inability to fix it, then I agree 21 with you. If you take away those qualifiers, then I 22 disagree with you.</p> <p>23 Q. Understood. Similar question to what I asked 24 you for Mrs. Alonso. Had Mrs. Wheeler had a 25 transvaginal mesh implanted by another medical device</p>

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<p style="text-align: right;">Page 653</p> <p>1 company, would you agree with me that she could still 2 have experienced the same exact problems that she's 3 complaining about today as a result of the implant of 4 the Bard Avaulta products?</p> <p>5 A. And I'll have to give the similar answer and 6 refer to my previous testimony on Alonso, but it's going 7 to be the same apply here because the Avaulta Solo 8 has -- is heavyweight, small pore arms compared to the 9 other products out there that I am familiar with, then 10 we can reasonably say, based upon the literature like 11 Clobb -- Cobb, Klosterhalfen, and others, that the 12 potential for complications will be greater with the 13 Avaulta Solo than the other mesh products. However, the 14 mesh -- other mesh products have a high degree of 15 complications with it. And it is my opinion no 16 transvaginal pelvic organ prolapse mesh, polypropylene, 17 with arms is safe.</p> <p>18 Q. Okay. So, in this case, Mrs. Wheeler's case, 19 you can't say that her outcome would have been any 20 different had she been implanted with another type of 21 pelvic organ prolapse device?</p> <p>22 MS. GAYLE: Objection. Form.</p> <p>23 BY MS. GEIST:</p> <p>24 Q. Correct?</p> <p>25 A. That's what I just stated.</p>	<p style="text-align: right;">Page 655</p> <p>1 inflammation and decreased the risk of erosion? 2 A. Number one, I do not recall ever seeing any 3 literature that supports that. I would like to see it. 4 That would be very interesting to read. But I did 5 review the other ones, roughly, 15 or 20 other articles, 6 talking about collagen placed in the woman's vagina 7 increases the immune system, increases hypersensitivity, 8 graft versus host disease, et cetera.</p> <p>9 Q. So you didn't -- in reaching this opinion, you 10 didn't review any literature or any article that 11 concluded that a collagen coating decreases an 12 inflammatory response during healing, which should, as a 13 result, decrease the risk of erosion?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. I would like to see that information. In my 17 review of the Bard internal documents, Bard depositions, 18 review of the available medical literature, I have not 19 found that. I have seen claims on Bard documentations, 20 but I have not seen any data to support that. However, 21 I keep an open mind. I would like to see that data.</p> <p>22 Q. Dr. Elliott, I want to move on now to the 23 third case in which you provided an expert opinion, 24 Mrs. Bolyard's case. Does anybody need a break?</p> <p>25 A. No. They're fine.</p>
<p style="text-align: right;">Page 654</p> <p>1 Q. Okay.</p> <p>2 A. I said that there is, regardless of which 3 company's device is placed, there is still the 4 possibility of devastating, irreversible complications. 5 The Avaulta Solo has a higher chance because of the 6 heavyweight, small pore arms.</p> <p>7 Q. And before you told me earlier that you're 8 distinguishing the Avaulta Solo from the Avaulta Plus; 9 is that right?</p> <p>10 MS. GAYLE: Objection. Form.</p> <p>11 BY THE WITNESS:</p> <p>12 A. That is correct on this one because it was 13 Avaulta Solo, which was implanted in Ms. Wheeler, did 14 not have the collagen implant.</p> <p>15 Q. And, in your opinion, the 16 collagen/polypropylene combination puts a woman at a 17 greater risk for adverse events because of the collagen 18 addition?</p> <p>19 A. Correct. Based upon the literature that is 20 available, the collagen content on the mesh, which is 21 backed up by internal documents from Bard, has an 22 increased risk for delayed healing, impaired healing.</p> <p>23 Q. Did -- in reaching that opinion, did you 24 consider any literature that concluded that the addition 25 of the collagen actually helped and decreased</p>	<p style="text-align: right;">Page 656</p> <p>1 Q. You keep answering for everyone, Dr. Elliott.</p> <p>2 A. That's okay. That's okay to use this?</p> <p>3 MS. GAYLE: You can look at it real quick.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. Sorry. I'm making a lot of noise.</p> <p>6 MS. GAYLE: What's our time on the record?</p> <p>7 VIDEO TECHNICIAN: 3:39.</p> <p>8 MS. GEIST: 3:39. What was my goal? Two hours per 9 case. I'm doing a lot better than I could have even 10 hoped.</p> <p>11 Madame Court Reporter, please tell me what 12 number I'm up to.</p> <p>13 THE REPORTER: 35.</p> <p>14 (Elliott Deposition Exhibit No. 35 15 was marked for identification.)</p> <p>16 THE WITNESS: I don't see 32 on that list. Do you 17 have one?</p> <p>18 THE REPORTER: I think she skipped it.</p> <p>19 THE WITNESS: That's fine. God is in the details.</p> <p>20 BY MS. GEIST:</p> <p>21 Q. Okay. Dr. Elliott, we're going to shift now 22 and talk about your opinions in the case of Patricia 23 Bolyard. And so I've marked, as Exhibit 35, a copy of 24 your expert report in that case. Do you need a copy, 25 Counsel?</p>

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<p>1 MS. GAYLE: Sure.</p> <p>2 MS. GEIST: This will be 35.</p> <p>3 MS. GAYLE: Thank you.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. And, Doctor, just by way of summary, can we agree for any issues that we've already discussed with respect to Mrs. Alonso and Mrs. Wheeler, those apply, also, to Mrs. Bolyard's case to the extent they're consistent?</p> <p>10 A. Correct. Correct, they are.</p> <p>11 Q. And can I also assume, Doctor, that your methodology that you employed in reaching your expert opinions in Mrs. Bolyard's case are the same as we already talked about extensively when we discussed Mrs. Alonso's case?</p> <p>16 A. Yes. My previous testimony of the evaluation, the differential diagnosis, will all be the same with these. And, also, for the record, on page 2 of the report, it's under the Subsection 2, and it's case-specific, it says, at the time of her 2008 Avaulta placement. It's actually July 2nd of 2010.</p> <p>22 Q. Correct.</p> <p>23 A. There is a typographical error there.</p> <p>24 Q. Okay.</p> <p>25 A. Just for clarification, so...</p>	<p style="text-align: right;">Page 659</p> <p>1 Mrs. Bolyard's case, the last page of your report there, 2 that's the list of medical records specific to 3 Mrs. Bolyard that you reviewed to inform your opinions 4 in her case, correct?</p> <p>5 A. Yes. On page 12, I assume you're referring 6 to, that is the records I reviewed.</p> <p>7 Q. Okay. You know what? My version, Doctor, 8 actually doesn't have a page 12. It's actually on 9 page 2.</p> <p>10 A. Okay. It just says, Exhibits for patient of 11 Bolyard. It says documents reviewed, and it has a list 12 of medical documents.</p> <p>13 Q. Okay.</p> <p>14 A. Actually mine is incomplete.</p> <p>15 Q. Did -- in your review of Mrs. Bolyard's case, 16 did you read any depositions taken in her case other 17 than the deposition of the plaintiff herself?</p> <p>18 A. Let me go to my reliance list. All I have 19 listened -- listed is the deposition of Patricia 20 Bolyard. I don't recall someone else's deposition, I 21 mean.</p> <p>22 Q. If you had read the depositions of any of the 23 treaters in Mrs. Bolyard's case, we would see that on 24 this list of documents reviewed?</p> <p>25 A. That's correct. It should list that. And it</p>
<p>1 Q. Thank you for that clarification. I should have asked you this for Mrs. Wheeler's report. So let me ask you for both cases, Mrs. Bolyard and Mrs. Wheeler's. These are both true and accurate copies of your report, and that's your electronic signature on both, correct?</p> <p>7 A. Correct.</p> <p>8 Q. Any other changes or revisions or typos needed to be corrected in either report?</p> <p>10 A. I believe, in Ms. Wheeler, also, on page 12, the last paragraph, it also mentions incorrectly having the Cook device implanted. It should be Bard device.</p> <p>13 Q. And that typo is in both of those case-specific reports, correct?</p> <p>15 A. Correct. Yeah, there is a typographical error.</p> <p>17 Q. Okay. So you've made that change on the record. And in Mrs. Wheeler's report, the copy that I marked doesn't have a copy of your CV or reliance list included in that copy. And I think, by agreement of counsel, we can just supplement that and include that to make the record complete and accurate?</p> <p>23 MS. GAYLE: That's fine with me.</p> <p>24 BY MS. GEIST:</p> <p>25 Q. Thank you. And so shifting back, again, in</p>	<p style="text-align: right;">Page 658</p> <p>1 also does not list the depositions of Dr. Ross and 2 Dr. -- Mr. Orr either. So it's somewhat incomplete. 3 But specific to Bolyard, it just has deposition -- 4 Patricia Bolyard's deposition.</p> <p>5 Q. Well, that -- the depositions of Dr. Ross and 6 Orr are listed in the list of materials you reviewed 7 provided with your generic report, correct?</p> <p>8 A. That is correct, yes.</p> <p>9 Q. For each of these reports, you have a separate 10 list of materials reviewed that are specific to that 11 individual plaintiff; fair to say?</p> <p>12 A. That is correct, yes.</p> <p>13 Q. And here for Mrs. Bolyard we don't see any 14 indication that you reviewed any of the deposition 15 testimony provided by any treating physicians in the 16 case, correct?</p> <p>17 A. Yeah. There is nothing listed here. I don't 18 recall if I reviewed something of the surgeon or not, 19 but there is nothing listed here.</p> <p>20 Q. Would that have been important information for 21 you to review in order to inform your opinions in the 22 case?</p> <p>23 A. I think it would be --</p> <p>24 MS. GAYLE: Objection. Form.</p> <p>25 BY THE WITNESS:</p>

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<p style="text-align: right;">Page 661</p> <p>1 A. I think it would be additive to the fund of 2 knowledge.</p> <p>3 Q. But you didn't do that in this case?</p> <p>4 A. I'm saying I don't recall if I did or not.</p> <p>5 Q. Do you know if any of the information in those 6 depositions would have changed your opinions in 7 Mrs. Bolyard's case?</p> <p>8 MS. GAYLE: Objection. Form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I would have to see those depositions.</p> <p>11 Q. So, sitting here today, you don't know one way 12 or another if your opinions would have been changed by 13 reviewing what the treaters had to say?</p> <p>14 A. I've been able to review their medical 15 documents. I've been able to review the medical 16 literature. I've been able to examine the patient 17 specifically. So the possibility of them altering my 18 opinion would be very small to none.</p> <p>19 Q. Okay. With respect to Mrs. Bolyard, she had 20 implanted, back on July 2nd, 2010, by Dr. Prouty the 21 Avaulta Solo anterior and posterior products, correct?</p> <p>22 A. That is correct.</p> <p>23 Q. No Align sling in this case, correct?</p> <p>24 A. There was no documentation of that in the 25 records.</p>	<p style="text-align: right;">Page 663</p> <p>1 to lichen sclerosis. It should be pelvic skin pain.</p> <p>2 MS. GAYLE: Hold up one moment, Doctor. Can you 3 spell that for Madame Court Reporter.</p> <p>4 THE WITNESS: Oh, lichen sclerosis? L-I-C-H-E-N, 5 and the next word is, sclerosis, S-C-L-E-R-O-S-I-S.</p> <p>6 (Sic.)</p> <p>7 BY MS. GEIST:</p> <p>8 Q. So let's go to page 2 of your report in 9 Mrs. Bolyard's case, Doctor.</p> <p>10 A. Okay. I'm there.</p> <p>11 Q. This is a list of your opinions, correct?</p> <p>12 A. On page 2?</p> <p>13 Q. I'm on page 5.</p> <p>14 A. Oh, yes.</p> <p>15 Q. Okay. And what -- tell me, again, what 16 exactly you need to change or amend in your report with 17 respect to the -- is it lichen or lichen?</p> <p>18 A. Lichen sclerosis.</p> <p>19 Q. Lichen sclerosis?</p> <p>20 A. Yes. Number one, I say pelvic pain secondary 21 to lichen sclerosis. It's pelvic skin pain. Lichen 22 sclerosis is a superficial disorder of the skin. I left 23 out skin there. And that has -- that has not been 24 caused by Avaulta. It's not been provoked by Avaulta. 25 It's a preexisting condition.</p>
<p style="text-align: right;">Page 662</p> <p>1 Q. Okay. You would have seen that somewhere in 2 the records if she had an Align sling implanted to 3 relieve stress urinary incontinence symptoms, correct?</p> <p>4 A. It should be in there, and it was not noted.</p> <p>5 Q. Okay. So same question that I asked you in 6 Mrs. Wheeler's case. Any of your opinions relating to 7 the Bard Avaulta Plus product and your opinions relating 8 to the collagen-polypropylene combination product would 9 not apply to Mrs. Bolyard's case, true?</p> <p>10 A. That -- that is correct. Anything pertaining 11 specifically to the collagen implantation do not apply 12 to Ms. Bolyard.</p> <p>13 Q. And, in Mrs. Bolyard's case, like I did with 14 your other cases, I'm going to just try and summarize 15 your opinions. And in her case, your opinions are that, 16 due to the Bard Avaulta product, she is experiencing 17 pelvic pain dyspareunia, urge incontinence, pelvic floor 18 myalgia, and then we have that same paragraph regarding 19 the impact on loss of physical intimacy and potential 20 for long-term depression, correct?</p> <p>21 A. Correct. She also -- she -- her current 22 diagnosis also is pelvic skin pain secondary to lichen 23 sclerosus, which has nothing -- that is not caused by 24 the Avaulta product. That is a preexisting condition. 25 Again, it states, in number one, pelvic pain secondary</p>	<p style="text-align: right;">Page 664</p> <p>1 Q. And lichen sclerosis is a fairly rare 2 condition, would you agree with me on that?</p> <p>3 A. Yes, it is a rare condition.</p> <p>4 Q. And the symptomatology associated with lichen 5 sclerosis is burning and cutting pain in the vaginal 6 region?</p> <p>7 A. In the skin, yes. It's a skin disorder.</p> <p>8 Q. That causes burning and cutting pain, correct?</p> <p>9 A. On the skin, yes.</p> <p>10 Q. Well, it can also result in painful sexual 11 intercourse or dyspareunia, correct?</p> <p>12 A. It can result in insertional pain at the skin 13 level.</p> <p>14 Q. Well, that's well established by the medical 15 literature; is it not?</p> <p>16 A. Yes. But the clarifier on there, it does not 17 cause pelvic floor myalgia. It does not cause deep 18 insertional pain. It's superficial skin pain at the 19 level of the introitus.</p> <p>20 Q. But you would agree with me, as set forth here 21 in your expert report in Mrs. Bolyard's case, that this 22 is a separate and independent reason for Mrs. Bolyard's 23 pelvic pain that has nothing to do with the Bard Avaulta 24 products; is that true?</p> <p>25 A. Bard is not responsible for causing lichen</p>

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<p style="text-align: right;">Page 665</p> <p>1 sclerosis, not cause for flare-up of the lichen</p> <p>2 sclerosis. This is a skin disorder on the outside of</p> <p>3 the vagina, which, again, has not been caused by Bard</p> <p>4 products.</p> <p>5 Q. And this is a condition that Mrs. Bolyard will 6 unfortunately have for the remainder of her life, true?</p> <p>7 A. To date there is no known cure for this</p> <p>8 process.</p> <p>9 Q. And I assume you saw in the medical records 10 that, prior to her implant of the Bard products, she had 11 rated her dyspareunia pain as a 7 out of 10, and that is 12 caused by the lichen sclerosis, correct?</p> <p>13 A. Correct. And that is insertional pain, a 7 on</p> <p>14 the Visual Analog Scale at the level of the skin. I</p> <p>15 agree with you.</p> <p>16 Q. And I believe she told you, when you saw her 17 and conducted your independent medical evaluation, that 18 her dyspareunia could be rated as an 8 out of 10; is 19 that correct?</p> <p>20 A. Where the -- we have to be careful, as far as</p> <p>21 what we're defining, I'm being very clear that Avaulta</p> <p>22 and Bard products are not responsible for lichen</p> <p>23 sclerosis. They are responsible for the deep pain</p> <p>24 inside of Ms. Bolyard's vagina.</p> <p>25 Q. Well, we can agree, from the medical records,</p>	<p style="text-align: right;">Page 667</p> <p>1 that pain is.</p> <p>2 Q. Is there any distinguishing information in her</p> <p>3 medical records that talk about the location of the</p> <p>4 pain, or does she just say, I have had pain -- painful</p> <p>5 sexual intercourse before ever being implanted with the</p> <p>6 Bard product that I rate on a scale of 7 out of 10?</p> <p>7 MS. GAYLE: Object to form.</p> <p>8 BY THE WITNESS:</p> <p>9 A. Well, lichen sclerosis is a disease of the</p> <p>10 skin. It's not a disease of the vagina. So it is in</p> <p>11 the medical records. There is no reason for her to have</p> <p>12 deep vaginal pain or obturator foramen pain, but she</p> <p>13 would have skin pain.</p> <p>14 Q. And she complains of this in terms of painful 15 sexual intercourse preimplant? That's in the records, 16 correct?</p> <p>17 A. Correct.</p> <p>18 Q. And then, after the surgery in July of 2010 19 where Mrs. Bolyard was implanted with the Bard products, 20 we see that she is now complaining of dyspareunia pain 21 and she rates it as an 8, 8 out of 10, postimplant, 22 correct?</p> <p>23 A. That is what I state, yes.</p> <p>24 Q. Okay. So we've moved from 7 out of 10 25 preimplant to 8 out of 10 postimplant?</p>
<p style="text-align: right;">Page 666</p> <p>1 that Mrs. Bolyard's lichen sclerosis was causing her, as 2 reflected in her records, painful intercourse or 3 dyspareunia and she rated it as a 7 out of 10 4 preimplant, correct?</p> <p>5 A. Correct, at the level of the skin.</p> <p>6 Q. Well, she --</p> <p>7 A. The introitus.</p> <p>8 Q. -- doesn't say anywhere in her records -- she 9 doesn't distinguish dyspareunia, as you are now, by 10 saying, well, it's only at the level of the skin, does 11 she?</p> <p>12 MS. GAYLE: Object to form and move to strike.</p> <p>13 BY THE WITNESS:</p> <p>14 A. Lichen sclerosis is not a disorder on the</p> <p>15 inside of the vagina. It will not distort the vagina.</p> <p>16 It will distort the introitus, the opening of the</p> <p>17 vagina.</p> <p>18 Q. Understood. But in Mrs. Bolyard's own 19 records, she has told her treating doctors, prior to 20 ever being implanted with the Bard product, that her 21 dyspareunia pain could be rated on a scale of 0 to 10. 22 She rated it as a 7 out of 10. That's what the records 23 show, correct?</p> <p>24 A. Yes. The records state that and with the</p> <p>25 understanding we have to define where the location of</p>	<p style="text-align: right;">Page 668</p> <p>1 MS. GAYLE: Object to form.</p> <p>2 BY MS. GEIST:</p> <p>3 Q. Fair summary?</p> <p>4 A. But there is a location difference, but the</p> <p>5 overall pain level has increased.</p> <p>6 Q. Can you point me to any medical record that 7 supports what you just told me, that there is a 8 difference in where she's experiencing the pain?</p> <p>9 A. Well, it's based upon my exam of her.</p> <p>10 Q. Well, her medical records, prior to her 11 implant, just say, I have pain with sexual intercourse. 12 I rate it as a 7 out of 10; isn't that true?</p> <p>13 MS. GAYLE: Object to form.</p> <p>14 BY THE WITNESS:</p> <p>15 A. Well, prior to the surgery, and the surg--</p> <p>16 the doctor is just documenting that she has painful</p> <p>17 intercourse.</p> <p>18 Q. Right.</p> <p>19 A. They have not delineated where that pain is.</p> <p>20 Q. Okay. Let's shift and talk about 21 Mrs. Bolyard's smoking history. I noted, when you 22 provided us with your updated literature list and 23 bibliography, you had some articles on there relating to 24 smoking and the potential injury or impact smoking could 25 have on the human body?</p>

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<p style="text-align: right;">Page 669</p> <p>1 A. Correct.</p> <p>2 Q. Did you do a little bit more reading about 3 smoking and the potential negative impact smoking could 4 have on the human body in preparation for your 5 deposition?</p> <p>6 MS. GAYLE: Objection. Form. His opinions 7 regarding smoking were discussed yesterday. If you have 8 a specific question in relation to this patient, go 9 ahead.</p> <p>10 MS. GEIST: I am --</p> <p>11 MS. GAYLE: But it sounded in general to me.</p> <p>12 MS. GEIST: I think I'm entitled to get an answer 13 here. So I hope you're not instructing Dr. Elliott to 14 not answer my question.</p> <p>15 MS. GAYLE: I believe that's a general opinion, but 16 I didn't hear anything case specific with her. I think 17 you started off and then tailed off. But if you want to 18 read back the question, you can, but I believe it to be 19 a general question.</p> <p>20 MS. GEIST: Can you read back my question?</p> <p>21 MS. GAYLE: And the one before, Madam Court 22 Reporter.</p> <p>23 THE REPORTER: I'm sorry.</p> <p>24 MS. GAYLE: And the one before it. 25 (Record read as requested.)</p>	<p style="text-align: right;">Page 671</p> <p>1 transvaginal cases with meshes. There is no data that I 2 am aware of that smoking increases any wound healing in 3 nonsmoker's transvaginal repairs.</p> <p>4 Q. So if Mrs. Bolyard had had an abdominal 5 sacrocolpopexy instead of a transvaginal mesh procedure 6 to treat her anterior and posterior defects, she would 7 have been at an even greater risk of mesh extrusion as 8 demonstrated by the literature, correct?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. Incorrect. The literature is current smokers.</p> <p>12 There is no data out there that I am aware of on former 13 smokers.</p> <p>14 Q. So --</p> <p>15 A. But current and active smokers are at 16 increased risk.</p> <p>17 Q. So a woman who is an active smoker at the time 18 of her procedure is at an increased risk?</p> <p>19 MS. GAYLE: Object to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. For transvaginal repairs, but there is also 22 good data out there that stopping up to ten days prior 23 reduces that risk tremendously. So, again, in former 24 smokers, I know of no good data that says they're at an 25 increased risk.</p>
<p style="text-align: right;">Page 670</p> <p>1 MS. GAYLE: My objection stands.</p> <p>2 BY MS. GEIST:</p> <p>3 Q. All right. So let me just add, in preparation 4 for your deposition in this case, in Mrs. Bolyard's 5 case, where we have a plaintiff who has a very 6 significant and extensive history of smoking?</p> <p>7 MS. GAYLE: Thank you, Counsel.</p> <p>8 MS. GEIST: You're welcome.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I did not update my reliance or look at 11 documents in preparation for a deposition because I also 12 do sacrocolpopexies. Smoking is associated with an 13 increased risk of mesh extrusion, that I know of no data 14 that states that smoking is involved in impaired healing 15 with nonmeshes. So I have a natural interest in that.</p> <p>16 Q. Okay. So let me just make sure I understand 17 that. Mrs. Bolyard, because of her long-term and 18 extensive history of smoking, was at a greater risk for 19 mesh expulsion -- pardon me -- mesh exposure or erosion 20 as a result of her smoking history; is that fair to say?</p> <p>21 MS. GAYLE: Objection, form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. There is data in the sacrocolpopexy that 24 smoking can increase the risk of extrusion. I have 25 heard conflicting reports as far as with the</p>	<p style="text-align: right;">Page 672</p> <p>1 Q. Well, Doctor, is Mrs. Bolyard a former smoker?</p> <p>2 A. It states in here former smoker. And that 3 actually raises a good point. I would have to look at 4 the IFU to see if they warn. If there is data out 5 there, I would like to see it. Because if there is good 6 data out there that smoking increases risk of extrusion 7 or complications with meshes, then it should be in the 8 IFU. And to the best of my knowledge, and correct me if 9 I'm wrong, I have not read any deposition. There is 10 nothing in here about smoking. So I would like to know, 11 is there information out there.</p> <p>12 Q. But just so I'm clear, it's your opinion that 13 somebody who is a current smoker is at a higher risk or 14 at an increased risk of mesh extrusion based on the 15 smoking, correct?</p> <p>16 MS. GAYLE: Objection. Form. Mischaracterizes his 17 testimony.</p> <p>18 BY THE WITNESS:</p> <p>19 A. The data that I am familiar with is in 20 abdominal sacrocolpopexies current smokers there is 21 increased risk. I am not aware of consistent or 22 consistent -- consistent on transvaginal mesh repairs.</p> <p>23 Q. Any reason to think the data would be any 24 different or better with the transvaginal repair?</p> <p>25 A. Yes, because they're a different procedure.</p>

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<p style="text-align: right;">Page 673</p> <p>1 Q. Well, smoking, it has a negative impact and 2 damages the vasculature, correct?</p> <p>3 A. Correct. I think that that's a fair</p> <p>4 assessment.</p> <p>5 Q. And somebody who has a pack-a-day habit is at 6 a greater risk of damage to the vascular -- vasculature 7 than somebody who has a half pack a day compared to 8 somebody who smokes a cigarette or two a day?</p> <p>9 MS. GAYLE: Objection. Form.</p> <p>10 BY MS. GEIST:</p> <p>11 Q. The more cigarettes you smoke, the more damage 12 you're causing to your body? Isn't that something 13 that's noncontroversial, Doctor?</p> <p>14 MS. GAYLE: Objection. Form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. I don't know if there is any data that says at</p> <p>17 what point in time you cross that threshold of their</p> <p>18 being dangerous. And, again, I am reviewing the IFU</p> <p>19 right now, and I see nowhere in here a warning on</p> <p>20 smokers.</p> <p>21 Q. Well, Doctor, come on. Do you need a warning 22 in the IFU about smoking? Doesn't every medical doctor 23 who has gone through medical school and gone on to treat 24 patients know that smoking is dangerous and damages 25 your -- damages your system, your vasculature? You</p>	<p style="text-align: right;">Page 675</p> <p>1 information about smoking and that that would have been 2 information a doctor would need to read about in order 3 to be informed about the risk of smoking?</p> <p>4 A. I think it's not just my opinion. It's the</p> <p>5 FDA's opinion, and a patient needs to be aware that, if</p> <p>6 they are smoking, they are at an increased risk.</p> <p>7 Q. You've never worked with the FDA or been a 8 consultant to the FDA with respect to what needs to go 9 into an IFU or not go into an IFU, correct?</p> <p>10 MS. GAYLE: Objection. Form. This was ground that 11 we plowed yesterday.</p> <p>12 BY MS. GEIST:</p> <p>13 Q. Is that correct, Doctor? You've never been a 14 consultant for the FDA or worked with the FDA on what 15 should go into an IFU?</p> <p>16 MS. GAYLE: Same objection. I'm going to instruct 17 you not to answer that because you asked it yesterday.</p> <p>18 MS. GEIST: I didn't ask him that question 19 yesterday. We didn't talk about FDA consulting. And he 20 just raised FDA regulations and an opinion about what 21 the FDA would require. So my question is new.</p> <p>22 BY MS. GEIST:</p> <p>23 Q. Have you ever been a consultant or worked for 24 the FDA in -- on issues relating to what should be on a 25 label or an IFU?</p>
<p style="text-align: right;">Page 674</p> <p>1 don't need to be told that in the IFU, do you?</p> <p>2 MS. GAYLE: Move to strike the preface to questions 3 by counsel. Also, objection. Argumentative.</p> <p>4 BY THE WITNESS:</p> <p>5 A. According to the FDA Blue Book, the warning</p> <p>6 sections, if a company is aware, they have to warn the</p> <p>7 patients of all known issues. If smoking -- if they</p> <p>8 know smoking is increasing the risk of complications</p> <p>9 with the procedure, they have to warn it. They do warn</p> <p>10 with their trocars of the possibility of organ</p> <p>11 perforation. If I hold up a trocar and you look at it,</p> <p>12 that will perforate organs. You don't need any degree</p> <p>13 with that, but they warn it. So, subsequently, smoking,</p> <p>14 I don't know. So, again, it's not in here.</p> <p>15 Q. Since you raised the point, there is no 16 evidence that there was any trocar perforation or any 17 damage caused to Mrs. Alonso or Mrs. Wheeler or 18 Mrs. Bolyard based on the trocars used in any of those 19 cases, correct?</p> <p>20 MS. GAYLE: Object to form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. There is no evidence of organ perforation with</p> <p>23 all three of those that you mentioned from the trocars.</p> <p>24 Q. All right. So let's go back to smoking. Is 25 it your opinion that the IFU should have contained</p>	<p style="text-align: right;">Page 676</p> <p>1 A. I've --</p> <p>2 MS. GAYLE: Same objection.</p> <p>3 BY THE WITNESS:</p> <p>4 A. I have never been an employee of the FDA.</p> <p>5 Q. Or a consultant with respect to the IFU or 6 what information needs to go into a label?</p> <p>7 A. I have never been an employee nor a consultant</p> <p>8 of the FDA.</p> <p>9 Q. Now, back to smoking, would you agree with me 10 that the duration or the length of time that somebody 11 smokes would have an increase on the damage to the 12 vasculature; in other words, if somebody -- if somebody 13 who smokes for five years compared to somebody who 14 smokes for ten years or, in Mrs. Bolyard's case, 15 somebody who smokes for 50 years a pack a day, are they 16 not at a greater increased risk for damaging their own 17 vasculature system?</p> <p>18 A. I think the data supports not necessarily the</p> <p>19 duration of smoking, but the fact that an individual</p> <p>20 stops smoking.</p> <p>21 Q. Now, you keep saying that, Doctor.</p> <p>22 A. Because --</p> <p>23 Q. Is your -- I'm sorry. Were you not done?</p> <p>24 A. No. I'm sorry.</p> <p>25 Q. Is it your opinion that Mrs. Bolyard had</p>

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<p style="text-align: right;">Page 677</p> <p>1 stopped smoking before she was implanted with the Bard 2 Avaulta products?</p> <p>3 A. I would have to go back and look at the 4 literature. I don't recall. I'm going off of my notes 5 here, and it states she was a former smoker.</p> <p>6 Q. Well, what makes you think she was a former 7 smoker?</p> <p>8 A. I would have to look at the notes. At some 9 point in time, I must have saw that she had stopped 10 smoking.</p> <p>11 Q. If she was a current smoker at the time of her 12 implant surgery back in July of 2010, would that change 13 your opinions in the case?</p> <p>14 A. If -- if the consensus is that that's going to 15 impair healing, then it would change it because that's 16 all the more evidence it should have been on the IFU.</p> <p>17 Q. Isn't it well-known by the medical community 18 that smokers have a greater challenge with healing, 19 their healing is impaired because of their smoking, 20 current smokers?</p> <p>21 MS. GAYLE: Objection. Form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Not with transvaginal work without meshes. 24 There is no data to support that.</p> <p>25 Q. There is no data to support that?</p>	<p style="text-align: right;">Page 679</p> <p>1 Q. All right.</p> <p>2 A. But we're -- but we're not --</p> <p>3 Q. So, at least, there is some -- I'm sorry. Go 4 ahead?</p> <p>5 A. We are talking about native, non-mesh repairs. 6 I know of zero data that smoking increases the problems 7 of wound healing.</p> <p>8 Q. But you have seen that data in the context of 9 the abdominal sacrocolpopexy, which is a mesh procedure 10 done via the abdominal approach, correct?</p> <p>11 A. Which we have discussed the other day as a 12 completely separate procedure and it's transabdominal.</p> <p>13 Q. But you have seen that data, correct?</p> <p>14 A. Correct, for the transabdominal repair, but 15 not the transvaginal repair.</p> <p>16 Q. So can we agree that Mrs. Bolyard, had she had 17 the trans- -- sorry -- had she had the abdominal 18 sacrocolpopexy instead of the transvaginal mesh, she 19 would have been at an increased risk of erosion after 20 that operation?</p> <p>21 MS. GAYLE: Object to form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Well, you used the word erosion. It's 24 extrusion.</p> <p>25 Q. Sorry. Extrusion.</p>
<p style="text-align: right;">Page 678</p> <p>1 A. Zero data with transvaginal native repairs 2 that impairs healing.</p> <p>3 Q. But you don't think you can extrapolate the 4 general, well-established body of literature out there 5 that says smoking is bad and damages your vasculature 6 and causes challenges and delayed healing? You can't 7 take that literature and say, well, of course, those 8 same problems and challenges would apply to somebody 9 undergoing a transvaginal mesh surgery? You can't do 10 that?</p> <p>11 MS. GAYLE: Objection. Form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Studies have been done and they don't see an 14 independent variable study analysis on transvaginal work 15 to show that smoking increases the risk of poor wound 16 healing in transvaginal work without meshes.</p> <p>17 Q. Are there some studies -- are there some 18 studies that talk about the fact that smoking may 19 increase a problem with healing or result in delayed 20 healing in somebody who has had a transvaginal mesh 21 implanted?</p> <p>22 A. With meshes, I have seen some state -- some 23 data -- I have seen some data stating that it can 24 increase the risk and other data showing it does not 25 have any impact upon it.</p>	<p style="text-align: right;">Page 680</p> <p>1 A. The data that -- there is data out there. If 2 she would have had a different procedure and had the 3 abdominal sacrocolpopexy, that there would have been an 4 increased risk for extrusion in that procedure, which 5 she did not have.</p> <p>6 Q. And sitting here today, after reviewing 7 Mrs. Bolyard's medical records, it's your opinion that 8 she was not a current smoker at the time she had her 9 Bard Avaulta mesh implanted or any time thereafter?</p> <p>10 MS. GAYLE: Objection. Form and asked and 11 answered.</p> <p>12 BY THE WITNESS:</p> <p>13 A. I would have to go back and look at the 14 records. You know, according to my notes, I wrote down 15 here, it says that she was a former smoker.</p> <p>16 Q. Well, if the records show -- if you go back 17 again and you take a look and you see that the records 18 show that Mrs. Bolyard was a current smoker at the time 19 of her Bard -- at the time of her implant surgery and 20 continued to smoke thereafter, would that change your 21 opinions in this case concerning the causes of the 22 problems that she experienced after the implant?</p> <p>23 MS. GAYLE: Objection to form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. Well, as I mentioned, according to my</p>

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<p style="text-align: right;">Page 681</p> <p>1 knowledge, there is conflicting data smoking does 2 anything as far as transvaginal mesh work. And if she 3 were an active smoker and there is knowledge out there 4 by the company that that is going to impair healing, 5 that's got to be on the IFU and she's got to be warned 6 for that.</p> <p>7 Q. So if you -- if you go back and you take 8 another look at the records, Doctor, and you conclude 9 that Mrs. Bolyard was a current smoker at the time of 10 the implant, that wouldn't have any impact or change 11 your opinions in this case, whatsoever; is that what 12 you're telling me?</p> <p>13 MS. GAYLE: Objection. Objection. Form. 14 BY THE WITNESS:</p> <p>15 A. Well, I thought I just answered it. Because 16 in the precautions section of the IFU, they list things 17 about compromised immune system, prior abdominal pelvic 18 surgeries, they list quite a few issues here, but 19 nowhere in there is, again, smoking. So from Bard's 20 perspective, it must not have played a role.</p> <p>21 Q. If you go back and look at Mrs. Bolyard's 22 records and conclude that she was a current smoker at 23 the time of her surgery, would you consider that fact in 24 reaching your opinions regarding why she experienced the 25 complications that she's testified about?</p>	<p style="text-align: right;">Page 683</p> <p>1 A. CO -- 2 Q. Would you consider Mrs. Bolyard's COPD and 3 chronic cough in reaching your opinions in this case 4 that the Bard Avaulta products were the cause of her 5 complications?</p> <p>6 A. COPD, in and of itself, is a lung condition 7 which would have no bearing upon vaginal extrusion, 8 vaginal pain. It may increase the risk of recurrence of 9 a prolapse, but it's not going to cause the other 10 issues.</p> <p>11 Q. How about -- 12 MS. GAYLE: Before your next question, do you 13 mind if we take a short break? I think it would do 14 us all good because everybody is stuttering and so 15 forth.</p> <p>16 MS. GEIST: No, not at all. I'm happy to take a 17 break.</p> <p>18 VIDEO TECHNICIAN: We're off the record. The time 19 is 1:55 p.m.</p> <p>20 (A recess was had.)</p> <p>21 VIDEO TECHNICIAN: We're back on the record. The 22 time is 2:03 p.m.</p> <p>23 MS. GEIST: May I have my last question read back, 24 please, Madam Court Reporter.</p> <p>25 (Record read as requested.)</p>
<p style="text-align: right;">Page 682</p> <p>1 MS. GAYLE: Objection. Asked and answered. 2 BY THE WITNESS:</p> <p>3 A. I believe I've answered. I guess I'm confused 4 because I've been answering this multiple times. I 5 would have to look --</p> <p>6 Q. I wouldn't be asking it again, Dr. Elliott, if 7 you would answer my questions. And this has been going 8 on all day today and all day yesterday. If you would 9 answer my questions, we could move on. I just want to 10 know. I just want to know, did you consider the fact 11 that Mrs. Bolyard was a current smoker at the time of 12 the implant and had a 50-year, pack-a-day history, did 13 you consider that as an alternative cause of some of the 14 problems and complications she experienced after her 15 implant surgery?</p> <p>16 MS. GAYLE: Objection. Asked and answered. 17 BY THE WITNESS:</p> <p>18 A. I have in my notes here she is a former 19 smoker. I have no evidence of her being an active 20 smoker at the time of the implantation. So if you show 21 me data that she was an active smoker at the surgery, 22 then we can proceed. Otherwise, I'm going off of what 23 my notes are.</p> <p>24 Q. How about chronic obstructive pulmonary 25 disease or COPD?</p>	<p style="text-align: right;">Page 684</p> <p>1 BY MS. GEIST: 2 Q. Doctor, would somebody such as Mrs. Bolyard 3 who has a chronic cough as a result of her COPD be at a 4 greater risk for erosion or extrusion of the vaginal 5 mesh?</p> <p>6 A. I'm not aware of any data that would show for 7 extrusion of mesh, it increased risk of recurrence of 8 her prolapse.</p> <p>9 Q. Would you agree with me if she had had, for 10 example, a native tissue repair, because the native 11 tissue repair is not augmented with a synthetic mesh, 12 that she would have had a greater recurrence of prolapse 13 had she undergone that procedure based on her chronic 14 cough?</p> <p>15 A. Chronic cough is associated with a greater 16 recurrence of pelvic organ prolapse. I'm not aware of 17 any study comparing COPD and native and mesh repairs. 18 So I can't say if she would have a greater recurrence.</p> <p>19 Q. If she had had a native tissue, you can't say, 20 due to her chronic cough, that she would have had a 21 recurrence of the prolapse repaired by the native tissue 22 procedure?</p> <p>23 A. She -- she would have a higher chance of 24 recurrence of a pelvic organ prolapse regardless of what 25 type of repair she had because it's a chronic,</p>

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<p style="text-align: right;">Page 685</p> <p>1 repetitive process.</p> <p>2 Q. How about diabetes? Does somebody diagnosed 3 with diabetes have greater challenges with respect to 4 healing after a surgical procedure?</p> <p>5 A. I'm not aware of anything transvaginal as far 6 as increasing wound healing. Definitely transabdominal 7 and obesity can increase the risk of wound healing, but 8 that's on the abdomen and the skin.</p> <p>9 Q. Did you consider, in reaching your 10 differential, whether Mrs. Bolyard's diagnosis of 11 diabetes could have had an impact on her wound healing?</p> <p>12 A. Yes.</p> <p>13 Q. And did you eliminate that as a cause after 14 you considered it?</p> <p>15 A. Well, diabetes -- I am unaware of any study 16 demonstrating that diabetes, in the transvaginal mesh 17 group, increases the risk of extrusion. In my review of 18 the literature and my experience, I have not seen 19 anything like that. If there is data, I would like to 20 see it. So, yes, I did review that. I did consider it. 21 I did not find it being, based upon data, a causal 22 factor.</p> <p>23 Q. Only because you couldn't find any data 24 specific to a transvaginal -- strike that.</p> <p>25 Only because you couldn't find any data that</p>	<p style="text-align: right;">Page 687</p> <p>1 to realize and that's why you need to have a very good 2 understanding of neuroanatomy, which is exactly why, in 3 my fellowship on bladder and neuroanatomy and a member 4 of the International Pelvic Pain Society, you have to 5 look at the distribution of the nerves, where the nerves 6 go.</p> <p>7 Pain down the legs, the back of the leg, the 8 bottom of the foot, that type of pain is consistent with 9 degenerative disc disease that is not caused by an 10 Avaulta product. Pain inside the vagina at the 11 obturator foramen is not due to degenerative disc 12 disease.</p> <p>13 Q. So you don't think any of the pain complaints 14 that Mrs. Bolyard has can be attributed to the 15 degenerative disc disease? Is that your opinion?</p> <p>16 A. We have to be specific which pain we're 17 talking about. If we're talking about dyspareunia pain 18 on pelvic exam, that is not due to a degenerative disc 19 disease.</p> <p>20 Q. How about her generalized complaints of pelvic 21 pain?</p> <p>22 MS. GAYLE: Objection.</p> <p>23 BY MS. GEIST:</p> <p>24 Q. Could that be attributable to her degenerative 25 disc disease?</p>
<p style="text-align: right;">Page 686</p> <p>1 specifically looked at the impact of diabetes on wound 2 healing after a transvaginal surgery?</p> <p>3 MS. GAYLE: Objection. Form.</p> <p>4 BY THE WITNESS:</p> <p>5 A. No. There are many studies out there, 6 multivariate analysis studies, looking at diabetes, age, 7 obesity, transvaginal repairs, and also mesh repairs. I 8 have yet to see anything on a good quality, multivariate 9 study to demonstrate diabetes increases the risk of 10 vaginal extrusion.</p> <p>11 Q. But you agree that diabetes increases the risk 12 or increases problems associated with wound healing, 13 correct?</p> <p>14 A. In the setting of the abdomen.</p> <p>15 Q. Why wouldn't that apply to the vaginal 16 setting?</p> <p>17 A. Because there is no fat in the vagina. Fat is 18 the problem. Fat does not heal. There is no fat, no 19 adipose, in the vagina.</p> <p>20 Q. How about degenerative disc disease? Did you 21 consider Mrs. Bolyard's degenerative disc disease --</p> <p>22 A. Absolutely.</p> <p>23 Q. -- in reaching your opinions with respect to 24 her chronic pain?</p> <p>25 A. Absolutely. And that is a very important one</p>	<p style="text-align: right;">Page 688</p> <p>1 A. Degenerative disc disease usually is L2 -- 2 excuse me, L3, 4, 5. The nerve roots of that extend 3 down to the sciatic, which then extend down the back of 4 the leg, front of the thigh, and the bottom of the foot. 5 And that is not the type of pain that she is 6 experiencing in the pelvis. The nerves have to be 7 involved going to the pelvis and they are not. Because 8 then we're talking about the pudendal nerve, and we have 9 no evidence of that being involved.</p> <p>10 Q. It's your opinion, Dr. Elliott, from your 11 expert report, that her pelvic pain is caused, at least, 12 in some degree, by her lichen sclerosis, correct?</p> <p>13 MS. GAYLE: Objection. Form. I believe he 14 corrected that on the report earlier.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Pelvic skin pain, perineum pain on the skin is 17 definitely due to lichen sclerosis. Avaulta, to the 18 best of my knowledge based upon neuroanatomy, study of 19 pelvic nerve neuroanatomy, the Avaulta product will not 20 be affecting the skin of the perineum.</p> <p>21 Q. So explain to me this difference you've been 22 talking about, the pelvic skin pain versus pelvic pain 23 generally. If I understand your report, you say that 24 the -- and this is based on your revision that we did 25 earlier, Mrs. Bolyard's pelvic skin complaint is</p>

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<p>1 secondary or caused by the lich- --</p> <p>2 A. Lichen sclerosis.</p> <p>3 Q. -- lichen sclerosis, correct?</p> <p>4 A. That is correct.</p> <p>5 Q. And her pelvic pain is caused by or secondary</p> <p>6 to the Avaulta mesh in your opinion, correct?</p> <p>7 A. Correct.</p> <p>8 Q. So explain to me just so I understand the</p> <p>9 difference in the two types of pain you're talking</p> <p>10 about?</p> <p>11 A. You have to understand neuroanatomy.</p> <p>12 Neuroanatomy is very logical. Nerves that are</p> <p>13 irritated, you can follow them back to wherever they</p> <p>14 are. Different nerves carry different stimuli, pain,</p> <p>15 temperature differences. On the skin they are carried</p> <p>16 by the dermatomes, which exit the back and wrap around,</p> <p>17 okay. That is not evolved by Avaulta product. The</p> <p>18 Avaulta product does not hit the skin dermatomes.</p> <p>19 Avaulta will hit the deep nerves, the nerves</p> <p>20 that are involved in the function of the bladder, a</p> <p>21 sensation deep within the vagina. So based upon my</p> <p>22 understanding of neuroanatomy and my education, they are</p> <p>23 completely separate entities.</p> <p>24 Q. And do you have any studies or scientific</p> <p>25 literature that you can cite to me in support of what</p>	<p>Page 689</p> <p>1 vaginal tissues?</p> <p>2 A. If the vagina were radiated during the healing</p> <p>3 period, the first six-or-so weeks afterwards, that</p> <p>4 possibly could play a role. If radiation is done</p> <p>5 afterwards, there is no data to support impaired</p> <p>6 healing.</p> <p>7 Q. She has -- Mrs. Bolyard has vaginal atrophy as</p> <p>8 well, correct? Did you see that in your review of her</p> <p>9 records?</p> <p>10 A. I say moderately atrophic.</p> <p>11 Q. She's been on Premarin and Estrace for that</p> <p>12 condition, correct?</p> <p>13 A. She's on Estrace. I don't know about vaginal</p> <p>14 Premarin. I don't recall. I would have to, again, look</p> <p>15 at the records to be specific. They're both vaginal</p> <p>16 estrogens regardless.</p> <p>17 Q. Okay. This isn't really surprising seeing as</p> <p>18 Mrs. Bolyard was a 70-year-old woman at the time of the</p> <p>19 procedure?</p> <p>20 MS. GAYLE: Objection. Form.</p> <p>21 BY MS. GEIST:</p> <p>22 Q. It wouldn't be unusual or atypical for a</p> <p>23 70-year-old woman to have vaginal atrophy?</p> <p>24 A. It's not beyond -- it would be consistent.</p> <p>25 It's not uncommon. I should put it that way.</p>
<p>1 you just said?</p> <p>2 A. Grey's Anatomy.</p> <p>3 Q. Anything else?</p> <p>4 MS. GAYLE: Objection. Form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. Clemente's Anatomy.</p> <p>7 Q. Did you consider the fact that Mrs. Bolyard</p> <p>8 was diagnosed with lymphoma shortly after her mesh</p> <p>9 implant surgery and underwent radiation therapy? Could</p> <p>10 the radiation therapy be a potential cause for her</p> <p>11 problems or challenges with wound healing?</p> <p>12 A. It depends where she got her -- it depends the</p> <p>13 timing of the radiation and the location of the</p> <p>14 radiation. I don't recall, off the top of my head,</p> <p>15 where she received radiation.</p> <p>16 Q. And did you look at that when you reviewed the</p> <p>17 medical records in the case to see whether or not it</p> <p>18 would potentially have an impact on her delayed healing?</p> <p>19 A. Yes, I did, and I just don't recall from the</p> <p>20 records, so we'd need to look at that. Lymphoma, if</p> <p>21 it's treated with radiation, usually is a pinpoint.</p> <p>22 They are radiating a certain location of the body. So,</p> <p>23 again, I would have to look, review the records to</p> <p>24 refresh my memory.</p> <p>25 Q. Could radiation therapy have an impact on the</p>	<p>Page 690</p> <p>1 Q. You note, in your report, Doctor, that</p> <p>2 Mrs. Bolyard was experiencing urge incontinence,</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. Are you attributing her urge incontinence to</p> <p>6 the Bard products?</p> <p>7 A. I cannot blame Bard fully for that condition.</p> <p>8 That condition can occur de novo. It could be</p> <p>9 exacerbated by the presence of the Bard product.</p> <p>10 Q. So I'm just trying to understand your opinion</p> <p>11 with respect to urge incontinence. You understand, from</p> <p>12 a review of the records, that that was a condition she</p> <p>13 had prior to the implant of the Bard products, correct?</p> <p>14 A. Correct.</p> <p>15 Q. Do you have an opinion in this case that the</p> <p>16 Bard products had any impact, whatsoever, on</p> <p>17 Mrs. Bolyard's urge incontinence?</p> <p>18 A. I would have to go back and look at my records</p> <p>19 here as far as the severity. If she had preexisting</p> <p>20 urge incontinence and the severity of that urge</p> <p>21 incontinence did not change afterwards; however, if it</p> <p>22 increased dramatically, then the blame could be placed</p> <p>23 upon the Avaulta product because the dissection of the</p> <p>24 vesicovaginal place -- space where the vesicovaginal</p> <p>25 plexus is, which is responsible for bladder function.</p>

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<p style="text-align: right;">Page 693</p> <p>1 Q. Sitting here today, do you have an opinion, to 2 a reasonable degree of medical certainty or probability, 3 that the Bard products played any role in Mrs. Bolyard's 4 development of urge incontinence?</p> <p>5 MS. GAYLE: Objection. Form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I'm looking at my records to see if I 8 documented severity change. I don't -- I don't see that 9 in there. Overreactive bladder, urge incontinence is a 10 very, very common condition, especially in this age 11 group. Again, I do not see a comparison of before and 12 afterwards. We would have to look at the records and 13 talk to the patient to find out if there has been a 14 change. If there has been only a minimal change, I am 15 agreeable with stating that the Bard product had minimal 16 impact upon that.</p> <p>17 Q. How about no impact? If there is no change 18 reflected in the records, how about agreeing with me 19 that the Bard product had no impact on her development 20 of urge incontinence?</p> <p>21 MS. GAYLE: Objection. Form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. If there has been no change or only minimal 24 change, I am acceptable with saying that the Bard had no 25 impact upon it right now. I don't know what happened on</p>	<p style="text-align: right;">Page 695</p> <p>1 currently. I don't recall, off the top of my head, how 2 sexually active she was before. It is a potential 3 significant impact upon her quality of life.</p> <p>4 Q. Well, it's only significantly -- it's only a 5 potential significant impact if she was actually 6 engaging in sexual intercourse prior to the implant of 7 the Bard products, correct?</p> <p>8 MS. GAYLE: Object to form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Again, I would have to refresh my memory and 11 look at the records as far as if she was sexually active 12 before. I don't recall.</p> <p>13 Q. Do you remember, from your review of the 14 records or review of the deposition testimony, that 15 Mrs. Bolyard's husband had erectile dysfunction 16 diagnosed years before the implant surgery?</p> <p>17 MS. GAYLE: Objection. Form. Mischaracterizes 18 testimony.</p> <p>19 BY THE WITNESS:</p> <p>20 A. Okay. Again, I'd have to look at that. I 21 have no reason to doubt it, but I would have to look at 22 the record and see what that says.</p> <p>23 Q. Well, if her husband was already having 24 problems engaging in sexual intercourse, this would have 25 an effect, would it not, on your opinion about her</p>
<p style="text-align: right;">Page 694</p> <p>1 down the road. But right now there's been no impact.</p> <p>2 Q. With respect to your opinion that the lack of 3 physical intimacy has already cost Mrs. Bolyard a major 4 component of her quality of life and similar to your 5 opinions in the other cases, you state that the 6 long-term impact on her quality of life is difficult to 7 accurately ascertain, but many studies have shown that 8 long-term negative impact leads to issues relating to 9 depression. And you hold that opinion with respect to 10 Mrs. Bolyard?</p> <p>11 A. Yes. And, hopefully, we can avoid the 12 discussion we've had on the previous two, because it's 13 going to be the exact same.</p> <p>14 Q. Yeah. I don't want to go over prior 15 discussion. So my only question on that point is, did 16 you consider the status of Mrs. Bolyard and her 17 husband's sexual activity in reaching that opinion prior 18 to the implant?</p> <p>19 A. You mean her degree of sexual activity prior 20 to?</p> <p>21 Q. Yeah. When you talk about the fact that she's 22 experiencing dyspareunia and that she can't have 23 physical intimacy and this is going to impact her 24 quality of life, correct?</p> <p>25 A. Yeah. And I state that, that she's not</p>	<p style="text-align: right;">Page 696</p> <p>1 quality of life after the implant?</p> <p>2 MS. GAYLE: Objection. Form.</p> <p>3 BY MS. GEIST:</p> <p>4 Q. Wouldn't you need to know to what extent the 5 couple was engaging in sexual intercourse as a married 6 couple?</p> <p>7 A. That's why I stated I would need to see what 8 the records state as far as her preop sexual activity 9 level.</p> <p>10 Q. Well, you've already rendered the opinion in 11 this case this lack of physical intimacy has cost her a 12 major component, she's unlikely to ever regain the 13 benefit of physical intimacy again, and that this impact 14 may have a long-term negative impact and potentially 15 depression, correct?</p> <p>16 Don't you have to -- in order to render such 17 an opinion, Doctor, don't you need to know what the 18 status of her sexual relations with her husband was 19 prior to the implant surgery?</p> <p>20 MS. GAYLE: Objection. Form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. Well, I state it on page 3. It says, prior to 23 her surgery, Ms. Bolyard was sexually active. However, 24 because of her diagnosis of lichen sclerosis, she did 25 describe pain with intercourse at introitus with</p>

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<p style="text-align: right;">Page 697</p> <p>1 insertion, and we have a reference number there.</p> <p>2 Q. So what's your -- what's the support for your 3 opinion that she was sexually active? Did you know that 4 her husband had erectile dysfunction that was diagnosed 5 prior to the implant?</p> <p>6 MS. GAYLE: Objection. Form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes. But, also, as a urologist, I'm also 9 aware people have different types of sex. So I'm just 10 going off of what I've been told in my questioning of 11 Mrs. Bolyard and comparing it, again, with her physical 12 exam. The same thing we've gone down before in the 13 other individuals.</p> <p>14 Q. Do you understand, from your review of 15 Mrs. Bolyard's records, that she had depression prior to 16 her surgery in 2010?</p> <p>17 A. I would have to refresh my memory off of the 18 medical records.</p> <p>19 Q. Well, did you consider her preexisting 20 condition of depression in reaching your opinions in 21 this case?</p> <p>22 A. Yes. And those individuals who all have 23 preexisting depression are probably at increased risk 24 with further stressors of worsening that depression, 25 more susceptible.</p>	<p style="text-align: right;">Page 699</p> <p>1 that her outcome would have been any different than it 2 is here. And I assume your answer would be the same 3 answer you gave me for Mrs. Alonso and Mrs. Wheeler; is 4 that also fair?</p> <p>5 A. That -- I'm sorry. Yeah. My testimony would 6 be consistent with -- consistent with the previous two.</p> <p>7 Q. In any of those three cases we just went over 8 together -- Mrs. Alonso, Mrs. Wheeler, and 9 Mrs. Bolyard -- did you review and observe any of the 10 mesh that had been excised from any of these three 11 plaintiffs?</p> <p>12 A. On one of the individuals, there is a Dr. 13 Ickelov report who has photos, and I cannot recall which 14 individual has those.</p> <p>15 Q. You didn't actually observe and do any 16 analysis of the excised mesh in Mrs. --</p> <p>17 A. Wheeler.</p> <p>18 Q. -- Alonso, Wheeler or Bolyard's case; is that 19 correct?</p> <p>20 A. I personally did not. I reviewed the slides 21 and the photos on Ms. Wheeler that were provided by 22 Dr. Ickelov.</p> <p>23 Q. So you didn't look at the actual mesh explants 24 or the mesh incised from any of the three plaintiffs; is 25 that correct?</p>
<p style="text-align: right;">Page 698</p> <p>1 Q. In Mrs. Bolyard's case, Dr. Elliott, would you 2 agree with me that, if she had had a native tissue or an 3 ASC procedure, she could have experienced the same 4 issues that she's complaining of today?</p> <p>5 A. Okay. My testimony is going to be identical 6 to the previous ones, which is much more detailed than 7 I'll be able to do now.</p> <p>8 Q. And you know what? If just want to stick with 9 your prior statements. And as long as you're telling me 10 that your opinions here would be the same as you gave me 11 for Mrs. Alonso and Mrs. Wheeler, I can agree to that 12 and we can shortcut it.</p> <p>13 A. Okay.</p> <p>14 MS. GAYLE: And my objections would also be the 15 same.</p> <p>16 MS. GEIST: That's fine.</p> <p>17 BY THE WITNESS:</p> <p>18 A. No. That would be -- I think I stated my 19 opinion well on the previous testimony, and it will be 20 the same as your line of questioning now. So I'm 21 agreeable to that.</p> <p>22 Q. Okay. And then my other question that I asked 23 you, with respect to Mrs. Alonso and Mrs. Wheeler, is 24 the same for Mrs. Bolyard. Had she had a transvaginal 25 mesh implanted from another manufacturer, you can't say</p>	<p style="text-align: right;">Page 700</p> <p>1 A. I did not personally hold that mesh or 2 personally do studies on that mesh. I did read the 3 report on Mrs. Wheeler by Dr. Ickelov and looked at the 4 photos of that mesh.</p> <p>5 Q. Okay. And I assume -- are you deferring to 6 any of the conclusions reached by Dr. Ickelov with 7 respect to Mrs. Wheeler's pathology?</p> <p>8 A. Yes. He has had a very thorough, detailed 9 write-up. I would defer to him on those issues.</p> <p>10 Q. Okay. He is a pathologist; is that right?</p> <p>11 A. Actually, his credentials I don't -- off the 12 top of my head, I can't recall. He's involved in 13 pathology. But, again, I -- I'd have to plead a little 14 ignorance. I can't recall.</p> <p>15 Q. Okay. So you're deferring to whatever he has 16 to say about the excised mesh of Mrs. Wheeler, correct?</p> <p>17 A. He has done microscopic evaluations on those. 18 I will defer to his opinions on that specific patient.</p> <p>19 Q. And you haven't reviewed any of the excised 20 mesh taken from Mrs. Alonso, Mrs. Wheeler, or 21 Mrs. Bolyard to reach any conclusion with respect to 22 degradation; is that correct?</p> <p>23 MS. GAYLE: Objection. Form.</p> <p>24 BY THE WITNESS:</p> <p>25 A. No. That is incorrect. Specifically, on</p>

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<p style="text-align: right;">Page 701</p> <p>1 Mrs. Wheeler, where there is documentation of 2 degradation, contraction, inflammatory process, I have 3 reviewed it and it is consistent with my physical exam 4 findings and my understanding of the available data out 5 there in manuscripts.</p> <p>6 Q. You don't have any opinion with respect to 7 degradation for Mrs. Bolyard and Mrs. Alonso; is that 8 correct?</p> <p>9 A. That is incorrect.</p> <p>10 Q. Well, you didn't review any of the slides or 11 anything like that for the excised mesh in those two 12 cases, correct?</p> <p>13 A. I did not personally examine those. However, 14 my physical exam, based upon my experience and knowledge 15 of the literature states that, when you have a firm, 16 gran- -- excuse me, not granulated -- nodule at the 17 level of the obturator foramen that is exquisitely 18 tender on exam, that is consistent with mesh degradation 19 caused by inflammation, inflammation causing pain.</p> <p>20 Q. And do you hold that opinion in each one of 21 these three cases we just talked about?</p> <p>22 A. Correct. My opinion would be consistent with 23 all three.</p> <p>24 Q. And your opinion is based on the physical 25 exam; is that correct?</p>	<p style="text-align: right;">Page 703</p> <p>1 A. I am describing that from when I take out 2 these tissue, these meshes, I hold them in my hands, I 3 have our pathologist review them, but they are -- 4 they're brittle, they crack, they're sharp, they can 5 poke you through the glove. You have to use very large 6 scissors, heavy-duty scissors to cut them out. To me, 7 that is clinical manifestations of degradation and the 8 cascade that happens from that.</p> <p>9 Q. So I think we're just -- I don't want to have 10 the record be confused. You didn't actually hold any of 11 the excised mesh from any of these three plaintiffs 12 which we've just talked about, correct?</p> <p>13 A. That is correct.</p> <p>14 Q. Okay. So I want to focus on the three 15 plaintiffs, okay?</p> <p>16 A. Okay.</p> <p>17 Q. You didn't look at any of the mesh removed 18 from any of these women under a microscope or look at 19 them at any point in time, correct?</p> <p>20 A. I -- well, with Ms. Wheeler, I looked at the 21 photographs and Dr. Ickelov's report. So, yes, I looked 22 at it. I did not personally look under a microscope at 23 them. Okay.</p> <p>24 Q. Including for Mrs. Wheeler, correct?</p> <p>25 A. Wheeler, only Wheeler.</p>
<p style="text-align: right;">Page 702</p> <p>1 A. Not just the physical exam. That's a very 2 good question. Not just the physical exam. I have to 3 correlate it with the available data that is out there, 4 Cobb, Klosterhalfen, others. There are many others 5 describing degradation of the tissues. Then correlating 6 that with my own surgical experience, even as of last 7 week of taking these things out, pulling them out, 8 they're brittle, they break, they're sharp, they're 9 painful, then correlating that with my physical exam I 10 do daily in my practice and correlating that with the 11 exams that I did on these three individuals.</p> <p>12 Q. And when you're talking about degradation, 13 you're talking about that from a clinician's perspective 14 and not a biomaterials expert perspective; is that fair 15 to say?</p> <p>16 MS. GAYLE: Objection. Form.</p> <p>17 BY THE WITNESS:</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 704</p> <p>1 Q. Wait. Hold on. This is not -- this is not 2 clear to me at all, Doctor. So let's go one step at a 3 time so we have a clear record.</p> <p>4 For Mrs. Alonso and Mrs. Wheeler and 5 Mrs. Bolyard, in any of those three cases, did you 6 actually visibly look at any of the excised mesh from 7 those three plaintiffs?</p> <p>8 MS. GAYLE: Objection. Form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. Again, just so we're clear, on Ms. Wheeler, I 11 have reviewed Dr. Ickelov's report, which includes in 12 there photographs of the specimens that have been taken 13 out of her.</p> <p>14 Q. So you looked at photographs that were 15 included in Dr. Ickelov's report?</p> <p>16 A. That is correct.</p> <p>17 Q. For Mrs. Wheeler?</p> <p>18 A. For just Mrs. Wheeler.</p> <p>19 Q. Okay. You didn't look at photographs with 20 respect to the mesh excised from Mrs. Bolyard or 21 Mrs. Alonso, correct?</p> <p>22 A. Correct.</p> <p>23 Q. You didn't look at pathology slides for any of 24 the three plaintiffs, correct?</p> <p>25 A. No. That's incorrect. I looked at the</p>

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<p style="text-align: right;">Page 705</p> <p>1 pathology slides on Mrs. Wheeler that were included in 2 Dr. Ickelov's report.</p> <p>3 Q. The photographs?</p> <p>4 A. The photographs of the pathologic specimen.</p> <p>5 Q. Understood. But you didn't actually look at 6 the slides. You didn't have the slide in your hand and 7 look at the mesh under a microscope for Mrs. Wheeler, 8 correct?</p> <p>9 A. No. I only looked at a photograph of the -- a 10 representative photograph of the specimen. I did not 11 personally sit at a microscope with a glass side and 12 look at it.</p> <p>13 Q. Okay. Thank you. Have you ever done that?</p> <p>14 Have you ever looked at excised mesh under a microscope?</p> <p>15 A. Yes.</p> <p>16 Q. Did you ever do that before you got involved 17 as an expert in the pelvic mesh litigation?</p> <p>18 A. Yes. In 2004, 2003, 2004, and then 2005 or 19 so, in my animal studies on the rabbits that we reviewed 20 yesterday.</p> <p>21 Q. Yes, and I remember those studies. So my 22 question was poor. Before you became involved in this 23 litigation as an expert for the plaintiffs, did you ever 24 look at excised mesh that had come from a woman's body 25 under a microscope?</p>	<p style="text-align: right;">Page 707</p> <p>1 Q. No. I'm not trying to. I'm just trying to 2 understand and I want to make sure the record is clear. 3 You've looked at photographs of slides that have been 4 reviewed by a pathologist or a biomaterials expert, 5 correct?</p> <p>6 MS. GAYLE: Objection. Asked and answered.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes. Of my own personal patients that I have 9 excised mesh and mesh complications, as part of my 10 routine, I review the pathologic specimens provided to 11 me by my pathology team. So I review those as part of 12 our routine.</p> <p>13 Q. So when you say the pathological specimens, 14 are you talking about slides or are you talking about 15 photographs?</p> <p>16 A. Photographs of the pathologic specimen.</p> <p>17 Q. Got it. So you've never looked at actual 18 pathology slides?</p> <p>19 A. I have --</p> <p>20 MS. GAYLE: Objection. Form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. I have not sat down with a glass specimen 23 looking under a microscope on the individuals I 24 reviewed. I look at the photographic representative the 25 pathologist provides me.</p>
<p style="text-align: right;">Page 706</p> <p>1 A. I have looked at the photograph of specimens 2 that my pathologists at my institution have provided for 3 the medical records on the ones that I have excised.</p> <p>4 Q. Okay. So the answer to my question is, no, 5 you, personally, Dr. Elliott, have not looked at excised 6 mesh under a microscope that came from a woman's body, 7 correct?</p> <p>8 MS. GAYLE: Objection. Form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. I have personally examined mesh excised from 11 our animal studies on the rabbit, which are documented 12 in two different publications. I have not sat down with 13 a microscope and looked at the slide specimens of the 14 individuals I have taken out. I have looked at the 15 photographs, representative photographs my pathologists 16 have given me, on individuals I've excised.</p> <p>17 Q. Okay. So I think we're talk -- I think we're 18 saying the same thing. You never actually looked at 19 slides under a microscope of excised mesh that came from 20 women, correct?</p> <p>21 MS. GAYLE: Objection. Form.</p> <p>22 BY THE WITNESS:</p> <p>23 A. Yeah. I answered that, and I answered it 24 very, very carefully because you're limiting what -- 25 what I just said.</p>	<p style="text-align: right;">Page 708</p> <p>1 Q. Okay. And the pathologist also, I assume, 2 provides you with a pathology report?</p> <p>3 A. Usually, yes. Yes, he does.</p> <p>4 Q. That's what a pathologist does? That's their 5 job?</p> <p>6 A. That is correct.</p> <p>7 Q. Okay. Back to Mrs. Bolyard's report, 8 specifically, Doctor, for a moment, on page 8 of this 9 report, the second paragraph --</p> <p>10 A. Yes.</p> <p>11 Q. -- this is the same paragraph that I referred 12 to you when we started your deposition today. Do you 13 remember that?</p> <p>14 A. I don't.</p> <p>15 Q. I realize it was some time ago.</p> <p>16 A. I don't remember that now.</p> <p>17 Q. Okay. This -- this paragraph, on page 8 of 18 Mrs. Bolyard's report, starts out by saying, Set out in 19 my general causation expert report, several 20 characteristics of the Marlex polypropylene mesh 21 rendering inherently unsafe for use in Ms. Bolyard. And 22 then you provide five specific reasons why you opine 23 that the characteristics of the Marlex polypropylene 24 mesh render it unsafe for use in Mrs. Bolyard?</p> <p>25 A. Correct.</p>

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<p style="text-align: right;">Page 709</p> <p>1 Q. And this is the same paragraph that's in 2 Mrs. Alonso's report and Mrs. Wheeler's report, correct? 3 A. Yes. 4 Q. And then, in the pages that we went over with 5 some frequency earlier, pages 8 to 11, these are all of 6 the things that you say should have gone into the IFU 7 for the Avaulta products, correct? 8 A. That is correct, and my previous testimony 9 correlates with this as well. 10 Q. And, in this section, you're basing your 11 opinion on what you think Bard knew and understood about 12 these risks based on the Bard internal documents that 13 you've included in your reliance materials? 14 A. Not just the internal documents, but also the 15 medical literature that was readily available. 16 Q. And you think -- well, let me ask you. Do you 17 believe that Bard intended to omit this information from 18 the medical community? Is that your opinion based on 19 your review of the internal Bard documents? 20 MS. GAYLE: Objection. Mischaracterizes his 21 opinions. 22 BY THE WITNESS: 23 A. I cannot -- I can only speculate what the 24 company was doing with this data in withholding it. I 25 can only have a theory.</p>	<p style="text-align: right;">Page 711</p> <p>1 MS. GAYLE: Objection. Form. 2 BY THE WITNESS: 3 A. It would depend upon what risk we're talking 4 about or what complication we're talking about. 5 Ignorance of risks and ignorance of literature is not an 6 excuse. So I can't give a carte blanche acceptance of 7 your statement. We'd have to go point by point. 8 Q. Well if a medical device company such as Bard 9 believed that there was no health consequence or risk, 10 it would be misleading to put that information on a 11 label. Would you agree with me on that? 12 MS. GAYLE: Objection. Form. 13 BY THE WITNESS: 14 A. I would want to see what that risk is and see 15 if I agree with the company that it is truly not a risk. 16 Q. Well, you have, in all of these expert reports 17 relating to the Marlex polypropylene mesh, you state, in 18 all of your reports, that Bard utilizes nonmedical grade 19 polypropylene, the supplier of which has forbidden its 20 use in humans because of its known degradation 21 characteristics. And then you say, in your IFU section, 22 that Bard should have included this information in the 23 IFU and told physicians about this. 24 Are those -- is that your opinion in this 25 case?</p>
<p style="text-align: right;">Page 710</p> <p>1 Q. Are you inferring Bard's intent from your 2 review of the records that you were provided in this 3 litigation? 4 MS. GAYLE: Objection. Question calls for a legal 5 conclusion. 6 BY THE WITNESS: 7 A. Yeah. I could only provide a theory of why 8 this was not provided in the form that I feel is 9 acceptable. That question would be best answered by the 10 Bard personnel. 11 Q. In the context of our discussion about all of 12 these risks that you think should be in the IFU, you 13 believe that a medical device company should include all 14 risks of which it is aware in the IFU; is that a fair 15 summary? 16 MS. GAYLE: Objection. Form. 17 BY THE WITNESS: 18 A. I believe that the requirements established 19 are that the company is required to provide all known 20 risks regardless of the severity. 21 Q. All right. So would you agree with me that, 22 if a medical device company is not aware of a risk, a 23 risk to an individual patient's health and well-being, 24 that they would not need to include that information in 25 the IFU?</p>	<p style="text-align: right;">Page 712</p> <p>1 A. Yes, as stated. 2 Q. And my question to you is, if Bard believed 3 that this was a hypothetical and not a real risk 4 relating to the Marlex polypropylene, should it have 5 included that information in the IFU? 6 MS. GAYLE: Objection. Calls for speculation. 7 BY THE WITNESS: 8 A. I think they owed -- they had a right. Excuse 9 me. The doctors and the patients, the doctor, who is 10 the implanter, and the woman that this is going to go in 11 the body, they are the ones who should be choosing that, 12 not the company. And if they had -- if they felt there 13 was no risk to this, then they should have done the 14 studies to show there was no risk. 15 Q. Well, you read the testimony from individuals 16 at Bard on this issue, the use of the Marlex 17 polypropylene, did you not? 18 A. I've read many depositions, yes. 19 Q. And so you read Bard's testimony that the 20 company did not believe that there was any medical or 21 scientific reason for the medical application caution in 22 the MSDS sheet for the Marlex polypropylene. Did you 23 read that? 24 MS. GAYLE: Objection. Form. I believe you all 25 discussed the MSDS yesterday.</p>

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<p>1 MS. GEIST: We did not.</p> <p>2 BY THE WITNESS:</p> <p>3 A. I have to go back. The actual manufacturer,</p> <p>4 Phillips Sumika, came out with that warning. I would</p> <p>5 assume that they are going to be the authority on this</p> <p>6 product. They are the manufacturer of the product.</p> <p>7 They issued the warning for a reason.</p> <p>8 Q. You say Phillips Sumika is the manufacturer of</p> <p>9 the product?</p> <p>10 A. Of the -- the Marlex substrate or the</p> <p>11 polypropylene substrate.</p> <p>12 Q. You understand that that MSDS sheet that</p> <p>13 you're referring to is not an MSDS sheet for the final</p> <p>14 Bard Avaulta product, don't you?</p> <p>15 MS. GAYLE: Objection. Form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. It is a warning for the basic fundamental</p> <p>18 building blocks of the mesh that's going to go into</p> <p>19 women.</p> <p>20 Q. It -- it relates to the raw material, the</p> <p>21 polypropylene pellet; is that a fair summary?</p> <p>22 MS. GAYLE: Continuing objection.</p> <p>23 BY THE WITNESS:</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 713</p> <p>1 A. Yeah. He was representing the company. The</p> <p>2 30(b)(6), I've never heard of that specific designation.</p> <p>3 I have no reason to disagree with that.</p> <p>4 Q. Did anybody ever tell you what that means to</p> <p>5 be a 30(b)(6) witness?</p> <p>6 MS. GAYLE: Objection. Form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. I don't -- I don't recall being told that.</p> <p>9 Q. Well, assume with me, Doctor, and I'll make</p> <p>10 this representation to you, that that means that that</p> <p>11 person is charged with speaking for the company on a</p> <p>12 particular topic and they need to be informed about that</p> <p>13 particular topic.</p> <p>14 A. Okay.</p> <p>15 Q. Okay. So assuming -- strike that.</p> <p>16 Assuming that the Phillips Marlex -- I'm</p> <p>17 sorry, the Phillips Sumika representative was a 30(b)(6)</p> <p>18 witness, somebody charged with speaking about that</p> <p>19 issue, why the medical application caution language was</p> <p>20 in the MSDS, assuming all of that, didn't that</p> <p>21 individual testify that he was not aware of any medical</p> <p>22 or scientific reason for the inclusion of that language</p> <p>23 in the MSDS sheet?</p> <p>24 MS. GAYLE: Continuing objection as to the form and</p> <p>25 to this entire line of questioning. You had your chance</p>
<p>1 A. That is just what I stated. It's the</p> <p>2 substrate, yes.</p> <p>3 Q. And did you read the testimony from Bard</p> <p>4 concerning why they believed that that was not a risk</p> <p>5 that needed to be included in the IFU or communicated to</p> <p>6 doctors? Did you review that testimony as I believe I</p> <p>7 saw in your reliance list?</p> <p>8 A. Yes. No. I've read it. I can't recall all</p> <p>9 of the details off the top of my head. I also read the</p> <p>10 deposition by the Phillips -- or Zumika (sic), whatever</p> <p>11 his name is, it starts with a Z. I've read his warning</p> <p>12 on it. And he says this is a warning.</p> <p>13 Q. You're referring to the testimony of Frank</p> <p>14 Zakrzewski -- and we can check the spelling after your</p> <p>15 deposition -- the representatives from the Phillips</p> <p>16 Sumika company?</p> <p>17 A. The salesperson that was test- -- that</p> <p>18 testified, yes.</p> <p>19 Q. And you were provided with that testimony,</p> <p>20 correct?</p> <p>21 A. Correct.</p> <p>22 Q. And you just said to me he is a salesperson.</p> <p>23 Did you understand, when you read it, that he was what</p> <p>24 we call a 30(b)(6) witness or a corporate representative</p> <p>25 on that issue?</p>	<p style="text-align: right;">Page 714</p> <p>1 yesterday. Y'all talked about an MSDS yesterday and</p> <p>2 this Marlex, and I think that this is going over ground</p> <p>3 that you already should have covered yesterday.</p> <p>4 MS. GEIST: Well, and I appreciate that objection,</p> <p>5 but we didn't talk about the MSDS at all yesterday. And</p> <p>6 it is contained in each one of these case-specific</p> <p>7 reports and as part of Dr. Elliott's opinions as to what</p> <p>8 should have been included and provided in the three</p> <p>9 implanting physicians in these three cases. So I'm</p> <p>10 entitled to explore it.</p> <p>11 BY THE WITNESS:</p> <p>12 A. I'll make the statement that, again, I'd have</p> <p>13 to -- I'm going off of memory, that he made the</p> <p>14 statement that he was not aware of studies or whatever.</p> <p>15 That does not mean that he was condoning it. And then</p> <p>16 he came back on deposition, page 205, lines 7 through 8,</p> <p>17 I view it as a warning that should be taken seriously.</p> <p>18 Q. Do you have the entirety of the testimony</p> <p>19 there?</p> <p>20 A. I don't have the entirety of the testimony</p> <p>21 here.</p> <p>22 Q. I think I saw, in your reliance list in these</p> <p>23 cases, that you also reviewed prior versions of the</p> <p>24 Phillips Sumika MSDS sheet, earlier versions?</p> <p>25 A. I'm -- I guess I'm not following. I've</p>

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<p style="text-align: right;">Page 717</p> <p>1 reviewed multiple different records, an earlier record.</p> <p>2 Q. I thought I saw in your reliance list, Doctor,</p> <p>3 that you had reviewed a number of different versions of</p> <p>4 the MSDS sheet; am I right about that?</p> <p>5 A. I've reviewed thousands of pages of documents.</p> <p>6 I can't -- I can't recall.</p> <p>7 Q. Okay. And I don't mean to be tricky. I'll</p> <p>8 just show them to you so we all are on the same page.</p> <p>9 MS. GEIST: Madame Court Reporter, what number am I</p> <p>10 up to?</p> <p>11 THE REPORTER: 36.</p> <p>12 (Elliott Exhibit Nos. 36, 37 & 38</p> <p>13 were marked for identification.)</p> <p>14 MS. GEIST: Counsel, would you like copies of</p> <p>15 these?</p> <p>16 BY MS. GEIST:</p> <p>17 Q. Doctor, I'm handing you what I've marked to</p> <p>18 your deposition as Exhibits 36, 37, and 38. And, for</p> <p>19 the record, these are copies of the Phillips Sumika</p> <p>20 Materials Safety Data Sheet, or MSDS. Exhibit 36 is the</p> <p>21 2007 version, Exhibit 37 is the 1993 version, and</p> <p>22 Exhibit 38 is the 1997 -- I'm sorry, 1997 version. And,</p> <p>23 Counsel, I'll give you copies in just a second. Do</p> <p>24 these look familiar to you?</p> <p>25 MS. GAYLE: Hold on, Counsel. I'm not letting him</p>	<p style="text-align: right;">Page 719</p> <p>1 or tissue?</p> <p>2 MS. GAYLE: Counsel, would you point him to</p> <p>3 where --</p> <p>4 BY THE WITNESS:</p> <p>5 A. That's what I'm trying to find. That's all.</p> <p>6 Q. Yeah. I'm trying to help you, Doctor. If you</p> <p>7 want to look at me down here, do you see it says Medical</p> <p>8 Application Caution, right here? (Indicating.)</p> <p>9 A. Oh, here it is.</p> <p>10 Q. There you go.</p> <p>11 A. Okay. Yes. Yes.</p> <p>12 Q. That's what you're talking about in your</p> <p>13 expert reports, right?</p> <p>14 A. Correct.</p> <p>15 Q. And you're saying -- well, you tell me. Are</p> <p>16 you saying, based on this, that Bard was told that this</p> <p>17 material should not be used in a permanent -- in a</p> <p>18 permanent implantation in a human body; and because Bard</p> <p>19 knew about this, they should have told doctors about</p> <p>20 this information. Is that your opinion?</p> <p>21 A. That's my opinion. I can't speak for Bard,</p> <p>22 but I can state that Phillips Sumika warned Bard of</p> <p>23 this.</p> <p>24 Q. And my question to you is, if Bard believed</p> <p>25 that there was no medical or scientific reason for that</p>
<p style="text-align: right;">Page 718</p> <p>1 look at them yet until I look at them.</p> <p>2 MS. GEIST: Sure. No. I have your copies here.</p> <p>3 Sorry, I'm a little slow. It's the end of the day.</p> <p>4 MS. GAYLE: I'm ready for my copies.</p> <p>5 BY MS. GEIST:</p> <p>6 Q. Do you -- do you have those three MSDS sheets</p> <p>7 in front of you?</p> <p>8 A. Yes, I do.</p> <p>9 Q. Dr. Elliott?</p> <p>10 A. Yes, I do.</p> <p>11 Q. Okay. Now, the one that you discussed, in</p> <p>12 each of your case-specific reports of Ms. Alonso,</p> <p>13 Mrs. Wheeler, and Mrs. Bolyard is the first one that</p> <p>14 I've marked as an exhibit to your deposition. This is</p> <p>15 the one that contains the medical application caution</p> <p>16 language, correct, the 2007 version?</p> <p>17 A. I don't see the language I'm familiar with.</p> <p>18 Q. Doctor, if you have the -- yeah, that's the</p> <p>19 right exhibit in front of you, the 2007 version. The</p> <p>20 language that you're talking about in your expert report</p> <p>21 is the medical application caution language, is it not?</p> <p>22 And, it says, on this exhibit, Do not use this Chevron</p> <p>23 Phillips Chemical Company material in medical</p> <p>24 applications involving permanent implantation in the</p> <p>25 human body or permanent contact with human body fluids</p>	<p style="text-align: right;">Page 720</p> <p>1 medical application caution language and it was included</p> <p>2 there for another reason that had nothing to do with</p> <p>3 patient safety, would Bard have any obligation to put</p> <p>4 that information in the IFU?</p> <p>5 MS. GAYLE: Object to form.</p> <p>6 BY THE WITNESS:</p> <p>7 A. I don't believe that is Bard's call to make.</p> <p>8 If this warning is here, the doctor and the patient need</p> <p>9 to be warned. And if Bard felt there was no problems</p> <p>10 with this, then I don't see why they were trying to hide</p> <p>11 it up on those series of e-mails. It's very</p> <p>12 well-documented where they're trying to hide it. That</p> <p>13 does not seem like what an upfront company would do.</p> <p>14 Q. Well, let's look at it. We just looked at the</p> <p>15 2007 version together, correct? That medical</p> <p>16 application caution, I just read it to you, right?</p> <p>17 A. Correct.</p> <p>18 Q. And underneath it, it says, Do not use this</p> <p>19 Chevron Phillips Chemical Company material medical</p> <p>20 applications -- and I'm going to skip a little bit --</p> <p>21 and then, it says, Unless the material has been provided</p> <p>22 directly from Chevron Phillips Chemical Company under an</p> <p>23 agreement which expressly acknowledges the contemplated</p> <p>24 use?</p> <p>25 MS. GAYLE: Objection. Form.</p>

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<p style="text-align: right;">Page 721</p> <p>1 BY MS. GEIST:</p> <p>2 Q. Do you see that information there, Doctor?</p> <p>3 A. Yes. That's what it states.</p> <p>4 Q. Did you review any materials or any</p> <p>5 information relating to Chevron Phillips entering into</p> <p>6 contracts with other medical device companies</p> <p>7 specifically for the use of this material in</p> <p>8 transvaginal mesh products?</p> <p>9 MS. GAYLE: Objection. Form. And objection,</p> <p>10 assumes facts not in evidence.</p> <p>11 BY THE WITNESS:</p> <p>12 A. I've heard of it with Boston Scientific.</p> <p>13 Q. So you're aware that Boston Scientific</p> <p>14 actually entered into a contract with the Phillips</p> <p>15 Sumika Company for this very same grade of Marlex</p> <p>16 polypropylene to use in their transvaginal products,</p> <p>17 transvaginal mesh products?</p> <p>18 MS. GAYLE: Objection. Form.</p> <p>19 BY THE WITNESS:</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 723</p> <p>1 MS. GAYLE: Objection. Form.</p> <p>2 BY THE WITNESS:</p> <p>3 A. He stated he was unaware, but that does not</p> <p>4 mean there is no data out there proving -- or there is</p> <p>5 data out there proving it's not an issue. He was</p> <p>6 unaware of anything.</p> <p>7 Q. Now, there is no citation to any medical study</p> <p>8 or literature supporting this application in the MSDS</p> <p>9 sheet itself, correct?</p> <p>10 MS. GAYLE: Objection.</p> <p>11 BY THE WITNESS:</p> <p>12 A. No. That would be best answered by a Phillips</p> <p>13 Sumika representative, which we have. He says, I view</p> <p>14 it as a warning. It should be taken seriously.</p> <p>15 Q. Have you ever seen any study looking</p> <p>16 specifically at the Phillips Sumika Marlex polypropylene</p> <p>17 and concluding that there was a medical or scientific</p> <p>18 reason that it should not be implanted in the human</p> <p>19 body? Have you ever seen any such study?</p> <p>20 MS. GAYLE: Objection.</p> <p>21 BY THE WITNESS:</p> <p>22 A. I don't recall with this specific grade of</p> <p>23 polypropylene Marlex. I don't recall ever seeing a</p> <p>24 study showing that it was safe.</p> <p>25 Q. Well, did you wonder why the Phillips Sumika</p>
<p style="text-align: right;">Page 722</p> <p>1 A. I cannot -- I cannot testify to that. I have</p> <p>2 not seen those records. I would like to see those</p> <p>3 records and correlate to that. But that still does not</p> <p>4 correlate. Just because Boston Scientific doesn't do</p> <p>5 it, doesn't mean Bard should do it. And they had this</p> <p>6 language here, and this does not excuse it.</p> <p>7 Q. Well, I'll show it to you in a minute. But my</p> <p>8 question is, do you think that, if the Phillips Sumika</p> <p>9 Company really believed that there was any safety issue</p> <p>10 relating to the implant of the Marlex polypropylene in</p> <p>11 the human body, that they would be providing it to</p> <p>12 Boston Scientific knowing full well what Boston</p> <p>13 Scientific intended to do with the material?</p> <p>14 MS. GAYLE: Objection, form and calls for</p> <p>15 speculation.</p> <p>16 BY THE WITNESS:</p> <p>17 A. I cannot speak for the interaction with Boston</p> <p>18 Scientific. We'd have to review all of those records.</p> <p>19 All I can state is what Frank Zakrzewski said. I view</p> <p>20 it as a warning. It should be taken seriously.</p> <p>21 Q. He also said, did he not, that he was unaware</p> <p>22 of any medical or scientific reason for the inclusion of</p> <p>23 this new language -- and this is what I want you to</p> <p>24 focus on -- the inclusion of this new language in the</p> <p>25 MSDS sheet? Didn't he also say that?</p>	<p style="text-align: right;">Page 724</p> <p>1 Company added this medical application caution language</p> <p>2 to the MSDS sheet?</p> <p>3 MS. GAYLE: Objection. Form and argumentative.</p> <p>4 Move to strike.</p> <p>5 BY THE WITNESS:</p> <p>6 A. The company, an oil company, issued this</p> <p>7 warning that their representative, who you've said is</p> <p>8 their official representative, he said, I view it as a</p> <p>9 warning. It should be taken seriously. So who do you</p> <p>10 want me to believe? You want me to strike Zakrzewski's</p> <p>11 statements. I mean, he states it. It's in here.</p> <p>12 Patients need to know that. Doctors need to know it.</p> <p>13 Q. Now, look with me, if you would, at the</p> <p>14 earlier versions of the MSDS sheets for the same</p> <p>15 material. And as we look at this, let me ask you this</p> <p>16 question. Were you aware of how many years Bard had</p> <p>17 been using this same polypropylene grade, the Marlex</p> <p>18 polypropylene grade, in its mesh products?</p> <p>19 MS. GAYLE: Objection. Form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. First of all, I have no evidence that this is</p> <p>22 the same grade. There are multiple different grades, I</p> <p>23 believe, in the 30s, different grades. All I know is</p> <p>24 HG6030-01 is the one referenced here. So I would want</p> <p>25 to see studies specifically with that grade stating it</p>

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<p style="text-align: right;">Page 725</p> <p>1 is safe coming from the company, and I don't see it. I 2 never saw that.</p> <p>3 Q. Now, if you look at the 1993 version of the 4 MSDS sheet, do you have that in front of you, Doctor?</p> <p>5 A. Yes, I do.</p> <p>6 Q. There is no medical application caution 7 language in that MSDS sheet?</p> <p>8 A. Okay. I would have to review through the 9 whole record. And, again, I have no idea if this is 10 pertaining to this specific grade.</p> <p>11 Q. I thought you looked at these materials 12 because they were on your reliance sheet. Have you not 13 seen these before?</p> <p>14 MS. GAYLE: Objection. Form. Argumentative. Move 15 to strike statement of counsel.</p> <p>16 BY THE WITNESS:</p> <p>17 A. No. I reviewed these, and I just stated that 18 I saw nothing in here to say that that is the exact same 19 grade that is discussed in the 2007 document.</p> <p>20 Q. Are you disputing that it's the same grade or 21 you just don't know?</p> <p>22 MS. GAYLE: Objection.</p> <p>23 THE WITNESS: I'm stating --</p> <p>24 MS. GAYLE: Move to strike.</p> <p>25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 727</p> <p>1 BY THE WITNESS: 2 A. No. I fully understand. And I fully 3 understand. And look at this, and, perhaps, this should 4 be addressed to the jury. Let them read this and ask 5 the women would you want to know this. I see 2007 the 6 specific grade that's implanted in women with warnings. 7 You then show me a document from 1993. I don't know 8 what the laws are. I don't know what the grade of this 9 is. I don't know if it's the same grades we're talking 10 about now. There is too much data that I don't know.</p> <p>11 Q. Does it -- on each of these three versions of 12 the MSDS sheet, doesn't it say, Marlex polypropylene, 13 all grades?</p> <p>14 MS. GAYLE: Object. Form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. Yes. All grades in 1993 does not mean all 17 grades in 2007.</p> <p>18 Q. Why not? It says all grades on this sheet?</p> <p>19 A. In 1993, if we say all Ford cars and in 1997 20 there are different types of cars around, so that does 21 not correlate. All grades, new warning. Perhaps, the 22 company has come up and found there are problems with 23 this.</p> <p>24 Q. Perhaps, or perhaps the company wanted to 25 limit its own liability and ensure that they were not</p>
<p style="text-align: right;">Page 726</p> <p>1 A. I'm stating I'd want to see the data that the 2 HGX030-01 has been proven safe and accepted by the 3 company for Bard to use in implantation of women.</p> <p>4 Q. If you flip through the 1993 version of the 5 MSDS sheet, can you agree with me there is no medical 6 application caution language anywhere in the document?</p> <p>7 A. Well, I see they have other health effects, 8 long-term exposure. The dust concentration can cause 9 non-debilitating lung changes.</p> <p>10 Q. Right. Do you understand -- let me back up 11 for a second, Dr. Elliott. Do you understand what an 12 MSDS -- MSDS sheet is?</p> <p>13 A. Yes. Yeah. It's the, you know, medical 14 device or Medical Safety Data Sheet, and this is your -- 15 you're showing me something from 1993, a long time ago, 16 and then you show me 2007 where they're making a 17 warning. Warnings change.</p> <p>18 Q. Well, it's not -- this has nothing to do with 19 a medical device, does it? This has to do with a 20 polypropylene pellet, a raw material that undergoes a 21 number of manufacturing processes before it is woven 22 into what ultimately becomes the Bard Avaulta mesh; do 23 you understand that?</p> <p>24 MS. GAYLE: Move to strike. Objection. Form. 25 Subject to that, you can answer, if you can.</p>	<p style="text-align: right;">Page 728</p> <p>1 getting embroiled in a product liability, personal 2 injury lawsuit; isn't that a possibility?</p> <p>3 MS. GAYLE: Object. Move to strike. Object, 4 argumentative.</p> <p>5 BY THE WITNESS:</p> <p>6 A. That sounds like a responsible company. And 7 that's when it gets scary, if an oil company of all 8 places is being more responsible on a product that goes 9 in a human body.</p> <p>10 Q. Do you think their own concern about their 11 liability equates with responsibility? Is that what 12 you're telling me?</p> <p>13 MS. GAYLE: Move to strike. Objection. Form. 14 Argumentative.</p> <p>15 BY MS. GEIST:</p> <p>16 Q. And then how are they responsible if they sold 17 this product, the Marlex polypropylene product, to 18 another medical device company, Boston Scientific, 19 knowing that Boston Scientific was going to use it in 20 their pelvic mesh product to treat prolapse?</p> <p>21 MS. GAYLE: Move to strike. Objection, 22 argumentative.</p> <p>23 BY MS. GEIST:</p> <p>24 Q. Isn't that inconsistent? I mean, if Phillips 25 Sumika sold the same grade of polypropylene to Boston</p>

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<p style="text-align: right;">Page 729</p> <p>1 Scientific, isn't that inconsistent with their not 2 selling it to Bard?</p> <p>3 MS. GAYLE: Objection, form. Objection, 4 argumentative, and move to strike.</p> <p>5 BY THE WITNESS:</p> <p>6 A. I have seen no records from Boston Scientific 7 to correlate that this is the same grade. That would be 8 helpful. I have seen no records from any deposition to 9 say -- saying it's safe. All I have is records saying 10 it's dangerous. I'm saying that the woman has the right 11 to know this is going in her body and a company is 12 warning her about it.</p> <p>13 Q. All right. I'll show you one more document, 14 Doctor, and then I think that will end our discussion on 15 the MSDS topic. And I'm up to exhibit what?</p> <p>16 THE REPORTER: 39.</p> <p>17 MS. GEIST: 39.</p> <p>18 (Elliott Deposition Exhibit No. 39 19 was marked for identification.)</p> <p>20 BY MS. GEIST:</p> <p>21 Q. Doctor, here is Exhibit 39. You've asked me a 22 couple of times to see this information. So my question 23 to you is, have you ever seen the information I've just 24 handed you for - which is marked as Exhibit 39?</p> <p>25 A. I don't recall if this is what I reviewed</p>	<p style="text-align: right;">Page 731</p> <p>1 answer.</p> <p>2 MS. GEIST: Well, this is the last document I'm 3 going to show him on the issue. We did not talk about 4 the MSDS issue at all during his deposition yesterday. 5 He puts front and center this issue, the nonmedical 6 grade polypropylene, in each and every one of his 7 case-specific reports. And he also discusses it in 8 terms of what he expected Bard to put in the IFU. And 9 it is not my fault that this is included in each and 10 every one of his specific causation reports.</p> <p>11 MS. GAYLE: It's incorporated --</p> <p>12 MS. GEIST: Now, I am -- and I am entitled to 13 explore whatever information he puts in his 14 case-specific reports.</p> <p>15 MS. GAYLE: It is incorporated into the 16 case-specific reports from his general report, and it's 17 gone over ad nauseam in his general report. And so we 18 have our two different positions on it. And I'll let 19 you go a little bit on this Exhibit 39, but not -- not 20 long. And then if you go too much further, I'm going to 21 instruct him not to answer.</p> <p>22 MS. GEIST: Well, that's fine. I already told you 23 I only plan on showing him one exhibit. I don't really 24 think either one of us believes that Dr. Elliott's 25 opinions are going to be changed by what I have to show</p>
<p style="text-align: right;">Page 730</p> <p>1 before Pinnacle. And how is this not on the general 2 liability? I don't understand this. We went over this 3 yesterday. You wasted time yesterday. Now we're 4 talking about this. So let's get into it.</p> <p>5 MS. GAYLE: No, Doctor. I believe that this is 6 general liability. You guys talked about this stuff 7 yesterday. You went over this.</p> <p>8 MS. GEIST: No, we did not. We did not talk about 9 MSDS, whatsoever.</p> <p>10 MS. GAYLE: Counsel, it's in his general report. 11 And, Doctor, will you step out of the room, please? 12 (Exit the witness.)</p> <p>13 MS. GAYLE: Counsel, it's our position that this is 14 in his general report and you were given the opportunity 15 yesterday to answer questions and ask questions related 16 to his general report. And the fact that you're 17 rehashing these general statements today we think is 18 beyond the scope of what he's here for today.</p> <p>19 Today he's here about case specifics. You're 20 not asking questions specific to those three individuals 21 and how it relates to his opinion. You're showing him a 22 document now, Exhibit 39, that even has to do with 23 Boston Scientific. Again, this is general matter, and 24 I'm -- I'm hesitant to do it, but I'm nearing the point 25 that I think I'm going to have to instruct him not to</p>	<p style="text-align: right;">Page 732</p> <p>1 him, but we're going to explore the issue. I think it's 2 only fair that he gets this full picture.</p> <p>3 MS. GAYLE: Okay. Can you go off the record for a 4 moment so I can go get him?</p> <p>5 VIDEO TECHNICIAN: We're off the record. The time 6 is 3:03 p.m.</p> <p>7 (A recess was had.)</p> <p>8 (Enter the witness.)</p> <p>9 VIDEO TECHNICIAN: We are back on the record. The 10 time is 3:09 p.m.</p> <p>11 BY MS. GEIST:</p> <p>12 Q. Doctor, you have Exhibit 39 in front of you?</p> <p>13 A. Correct.</p> <p>14 Q. Were you provided with this previously?</p> <p>15 A. I don't recall seeing this before.</p> <p>16 Q. Okay. If you go with me to look to the actual 17 third page of the document, it actually says, page 5, on 18 the top left corner. Do you see that?</p> <p>19 A. I'm on the third page. I'm on the third page.</p> <p>20 I don't see a page 5 anywhere, but I'm on the third page 21 of it.</p> <p>22 Q. Okay. Well, do you -- please take a look at 23 the front page of the document before we get to page 5. 24 I just want you to see that, in June of 2008, FDA asked 25 Boston Scientific about the MSDS they used for Marlex</p>

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<p style="text-align: right;">Page 733</p> <p>1 polypropylene resin purchased from Phillips Sumika. 2 A. Okay. I've never seen it. It's a 23-page 3 document, which I've never seen before, which, 4 obviously, this is a very important document. And so, I 5 mean, to be fair, I need to be able to review this.</p> <p>6 Q. Understood. And I'll give you as much time as 7 you want after I direct you to certain portions of the 8 document, and then you can take a look at it. Okay?</p> <p>9 A. Okay.</p> <p>10 Q. Is that fair?</p> <p>11 A. Potentially.</p> <p>12 Q. Okay.</p> <p>13 A. It's a 23-page document.</p> <p>14 Q. I understand. Some of it has topics in here 15 that don't really concern us and others do not, but 16 you're welcome to review the whole document. If you 17 look at the first page, or, you know, go towards the 18 last page, whatever makes sense to you, it's a document 19 that is coming from the Food & Drug Administration or 20 FDA, correct?</p> <p>21 A. Correct.</p> <p>22 Q. To Boston Scientific, correct?</p> <p>23 MS. GAYLE: Objection. Form. He's already asked 24 to review the whole document.</p> <p>25</p>	<p style="text-align: right;">Page 735</p> <p>1 representation. But this is from FDA to Boston 2 Scientific. And the FDA states, at No. 8, The Material 3 Safety Data Sheet provided for the Marlex material 4 states that the product used is for coatings. In this 5 MSDS, there is a medical application caution that states 6 do not use this Chevron Phillips Chemical Company 7 material in medical applications involving permanent 8 implantation in the human body or permanent contact with 9 internal body fluids or tissues. Did I read that 10 correctly?</p> <p>11 A. I see it.</p> <p>12 Q. That's the same language we just looked at 13 together, correct, for the Marlex polypropylene 14 material?</p> <p>15 A. It appears to be similar.</p> <p>16 Q. It's actually identical, but you can compare 17 the language in both. And the FDA says to Boston 18 Scientific, Please provide a rationale why your mesh 19 material is safe for use as a permanent implant device 20 contrary to what is stated in the MSDS provided for the 21 Marlex material. Do you see that?</p> <p>22 MS. GAYLE: Object to form.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I see that.</p> <p>25 Q. So the FDA is asking Boston Scientific, Hey,</p>
<p style="text-align: right;">Page 734</p> <p>1 BY MS. GEIST: 2 Q. Well, I'm just looking at the address. It's 3 addressed to Boston Scientific? 4 MS. GAYLE: It's a compilation of multiple 5 documents.</p> <p>6 BY THE WITNESS: 7 A. Yeah. I don't feel -- I mean, this is a 8 complicated -- it's a very important, complicated 9 document that is just now presented to me after we could 10 have reviewed this yesterday, and so -- and this is not 11 just one, and there's letters back and forth.</p> <p>12 Q. Doctor, I want to give you as much time as you 13 need to review it, but let me point you to certain 14 sections. And then, if you need more time, feel free. 15 If you go to -- do you see at the bottom there is what 16 we call Bates numbers?</p> <p>17 A. Yes, I see those.</p> <p>18 Q. Do you see they begin with DX?</p> <p>19 A. Yes.</p> <p>20 Q. If you go to the page that has DX0046-005?</p> <p>21 A. Yes, I see. I'm there.</p> <p>22 Q. Okay. Do you see at No. 8, paragraph 8?</p> <p>23 A. Yes.</p> <p>24 Q. And this is from FDA. And you can look at the 25 document to make yourself comfortable with my</p>	<p style="text-align: right;">Page 736</p> <p>1 we see this medical application caution language. We 2 want to understand why you think the mesh is safe to use 3 in the human body. Is that a fair summary?</p> <p>4 MS. GAYLE: Object to form.</p> <p>5 BY THE WITNESS:</p> <p>6 A. I see what they're stating in this one number 7 here, yes.</p> <p>8 Q. And then, if you flip with me a couple more 9 pages to the document at the bottom that has 009 --</p> <p>10 A. Okay.</p> <p>11 Q. -- and do you see, at the top, it says, 12 Response to FDA questions?</p> <p>13 A. Yes.</p> <p>14 Q. And it has FDA Question No. 8 below there, do 15 you see that?</p> <p>16 A. I see it.</p> <p>17 Q. And that's the same question that FDA had that 18 we just read previously, correct?</p> <p>19 A. I see it.</p> <p>20 Q. And, at the bottom, underneath that, it says, 21 BSC response, or Boston Scientific company response?</p> <p>22 A. I see it.</p> <p>23 Q. And with respect to the Marlex polypropylene 24 MSDS sheet, at the second paragraph, Boston Scientific 25 states that, in 2002, Boston Scientific was informed</p>

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<p style="text-align: right;">Page 737</p> <p>1 that Phillips Sumika no longer would supply this resin 2 for any application involving implantation in the human 3 body due to the company's unwillingness to accept any 4 liability for the use of their resin for medical 5 purposes, particularly permanent implants. They 6 subsequently revised the MSDS for Marlex to this effect. 7 Do you see that?</p> <p>8 A. Yes.</p> <p>9 MS. GAYLE: Object to form.</p> <p>10 BY MS. GEIST:</p> <p>11 Q. So do you see there Boston Scientific is 12 reporting to FDA that Phillips Sumika told them they 13 would not supply the polypropylene resin due to their 14 own concern for liability? And then underneath that, it 15 says, However, in 2004, Boston Scientific entered into a 16 one-year contract with Phillips Sumika to enable Boston 17 Scientific Corporation to purchase the resin with the 18 understanding that Boston Scientific would use this 19 material in the manufacture of medical devices which may 20 be implanted in the human body. The agreement required 21 Boston Scientific to be ultimately responsible for 22 ensuring that the material was suited to the specific 23 application and assume all product liability. Do you 24 see that?</p> <p>25 A. Yeah.</p>	<p style="text-align: right;">Page 739</p> <p>1 polypropylene manufacturer from product liability? 2 Knowing that, should they have communicated that to 3 doctors?</p> <p>4 MS. GAYLE: Object to form. Object to the 5 characterization of the Phillip Sumika's intent or 6 reasoning for putting that in there, and object to 7 counsel testifying on behalf of the company, and object 8 to the use of this document. We weren't provided this 9 previously. I don't even believe it's on his reliance 10 list, Counsel.</p> <p>11 MS. GEIST: Well, I understand that you all --</p> <p>12 MS. GAYLE: He's asked for the opportunity to 13 review it.</p> <p>14 MS. GEIST: -- didn't give your own expert this 15 information. That would have been helpful for a doctor 16 to know the full story.</p> <p>17 MS. GAYLE: That's an unfair characterization, 18 Counsel. In addition, he's asked to review the document 19 that you're trying to ask him questions for, and then 20 you're saying that the company -- you're testifying for 21 the company. They're trying to keep this out. It's 22 ridiculous. So my objection stands.</p> <p>23 BY THE WITNESS:</p> <p>24 A. I have yet to see a document which has Bard's 25 name on it saying it's okay to use in the implantation</p>
<p style="text-align: right;">Page 738</p> <p>1 Q. And then, ultimately, as I think you already 2 know, Doctor, from your own experience, FDA cleared, 3 through the 510 clearance process, the Pinnacle device, 4 which is the subject of this correspondence between FDA 5 and Boston Scientific?</p> <p>6 MS. GAYLE: Object to form.</p> <p>7 BY MS. GEIST:</p> <p>8 Q. Are you aware of that?</p> <p>9 A. I have no data to support that. I have not 10 seen those documents.</p> <p>11 Q. Well, it's part of this overall package, the 12 FDA's approval of the Pinnacle product. It's part of 13 this, Doctor. And I'm happy to have you read it cover 14 to cover.</p> <p>15 MS. GAYLE: And he's asked to review the document. 16 And so my objection continues with asking him questions 17 when he's not even reviewed the document.</p> <p>18 BY MS. GEIST:</p> <p>19 Q. And, Doctor, I guess my question to you is 20 this, after being informed of the reasons why the 21 Phillips Sumika Company added that medical application 22 caution language to the MSDS sheet, does that change 23 your opinion at all that Bard should have included that 24 information in the IFU for the Avaulta products knowing 25 that the only reason it was included was to insulate the</p>	<p style="text-align: right;">Page 740</p> <p>1 of humans. I see Boston Scientific everywhere.</p> <p>2 Q. Now, that is the same Marlex polypropylene 3 that we just looked at which is set forth in the MSDS 4 sheet for the Avaulta products, true?</p> <p>5 MS. GAYLE: Object to form.</p> <p>6 BY MS. GEIST:</p> <p>7 Q. If you compare -- if you look at the document 8 I just gave you, Doctor, and the MSDS sheet, it is the 9 same Marlex polypropylene? It is the very same, from 10 the very same company? Do you see that?</p> <p>11 A. I see that.</p> <p>12 Q. So does it matter whether or not there is 13 Bard's name on it, that Boston Scientific is telling FDA 14 exactly why Phillips Sumika added that language to the 15 MSDS sheet?</p> <p>16 MS. GAYLE: Object to form.</p> <p>17 BY THE WITNESS:</p> <p>18 A. I don't know of all of the manufacturing 19 processes that go on after the product is delivered to 20 Boston Scientific versus Bard. All I see here is Boston 21 Scientific. Boston Scientific gained permission. I 22 don't see Bard ever gaining permission, and they're 23 actually trying to hide that fact.</p> <p>24 Q. Does this document at all relieve your concern 25 that there was any scientific or medical reason for the</p>

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<p style="text-align: right;">Page 741</p> <p>1 inclusion of the medical application caution language in 2 the MSDS sheet to begin with?</p> <p>3 MS. GAYLE: Object to form.</p> <p>4 BY MS. GEIST:</p> <p>5 Q. I mean, you haven't seen a single document, an 6 article or a study, that caused the Phillips Sumika 7 company to put that language in the MSDS sheet, have 8 you?</p> <p>9 MS. GAYLE: Object to form.</p> <p>10 BY THE WITNESS:</p> <p>11 A. I've seen the opposite. I've seen the 12 representative of that company saying it should be taken 13 seriously.</p> <p>14 Q. So you're sticking with that opinion 15 regardless of what I just showed you; is that correct?</p> <p>16 MS. GAYLE: Objection. Mischaracterizes his 17 testimony. And moved to strike counsel's preface before 18 the question.</p> <p>19 BY MS. GEIST:</p> <p>20 Q. Do you want to at least review the materials 21 I've provided to you, Dr. Elliott, and see if that has 22 any impact on the opinions you've given in this 23 litigation to a reasonable degree of medical certainty?</p> <p>24 A. Yeah. It's 23 pages. For me to read that 25 will take at least two to three minutes per page, and I</p>	<p style="text-align: right;">Page 743</p> <p>1 A. No. That was at the Palmer Hotel where I'm 2 staying. And then last night I met with Ms. Gayle for, 3 roughly, 15, 20 minutes at the Palmer Hotel, again, 4 going over just discussion for today, and that's it.</p> <p>5 Q. Any other meetings with any other plaintiffs 6 to prepare for your deposition today?</p> <p>7 A. No.</p> <p>8 Q. Or yesterday?</p> <p>9 A. No. Just those two telephone calls that I can 10 recall. I believe that was all there was for, again, 11 roughly, whatever times I told you.</p> <p>12 Q. And, in terms of the total number of hours 13 you've spent reviewing information and preparing for 14 your deposition, that would be reflected in your 15 invoices to counsel, I assume?</p> <p>16 A. That's correct. That would be -- that would 17 be the accurate representation of the time that I spent 18 in totality on this project.</p> <p>19 Q. And would that provide a narrative that would 20 be helpful to somebody like me that actually say things 21 like preparation for deposition or similar language?</p> <p>22 A. Yes. It would have prepare -- preparation for 23 deposition and then review of pertinent manuscripts 24 could be the same thing. So it's not going to be just 25 specific just "deposition."</p>
<p style="text-align: right;">Page 742</p> <p>1 may -- I may have to correlate that. So that will be, 2 roughly, 45 minutes or longer, and I will do that.</p> <p>3 Q. I'm just saying. You don't have to do it now. 4 But my question to you is, would you want to review the 5 information I provided to you to see if it changes your 6 opinions at all?</p> <p>7 A. Absolutely.</p> <p>8 Q. Doctor, before your deposition today in the 9 three cases -- Mrs. Alonso's case, Mrs. Wheeler's case, 10 and Mrs. Bolyard's case -- can you just tell me briefly 11 what you did to prepare for your testimony?</p> <p>12 A. I reviewed medical literature, combining that 13 with my 20-some odd years of medical experience. I 14 reviewed depositions. I had an hour-and-12-minute 15 conversation with Mr. Cartmell in one day. I had an 16 hour-and-21-minute conversation the other day. I 17 reviewed my expert report, those things.</p> <p>18 Q. Those two conversations with Mr. Cartmell that 19 you just described to me, did you have any other 20 conversations or meetings with plaintiff's counsel to 21 prepare for your testimony today or yesterday?</p> <p>22 A. On Saturday morning, I met with Mr. Cartmell 23 for, roughly, 15 minutes.</p> <p>24 Q. And was that here at the Wexler Wallace's 25 offices, Wexler Wallace office in Chicago?</p>	<p style="text-align: right;">Page 744</p> <p>1 Q. Got it. And we've already asked for that 2 information, which has not yet been provided to us. 3 You're aware of that, correct?</p> <p>4 A. I'm not aware of that, no. I know you've 5 requested it. I've heard that, but I don't know what 6 you've received.</p> <p>7 Q. Okay. Sitting here today, I assume you can't 8 give me your best approximation or estimate of how much 9 time you actually spent preparing to give testimony 10 today and yesterday?</p> <p>11 MS. GAYLE: Objection. Form.</p> <p>12 BY THE WITNESS:</p> <p>13 A. Well, in reality, preparation for today began 14 20-something years ago. So you can't exclude that 15 experience, but then it also began in June or July, 16 whenever I began on this project, too.</p> <p>17 Q. Well, but you're not going to bill for time 20 18 years ago, though, right, Doctor?</p> <p>19 A. No. I'm not going to bill.</p> <p>20 Q. That would be a pretty big bill?</p> <p>21 A. So billing began in June, but preparation 22 began during fellowship, residency, medical school even. 23 So I know what you're saying, and I'm not trying -- but 24 I'm trying to also say this is not just preparation for 25 this. There has been a vast amount of preparation.</p>

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<p style="text-align: right;">Page 745</p> <p>1 Q. No. I understand that. I just didn't know if 2 you could tell me there was a specific day, for example, 3 where you said to yourself, Okay, I need to start 4 preparing for my deposition. Let me hunker down and go 5 through my reports and look at literature and things of 6 that nature?</p> <p>7 A. In reality, that probably would be -- sorry.</p> <p>8 In reality, that began probably the first day I reviewed 9 medical records. Because having going through this 10 process before, when I start looking at those things, 11 that is preparation.</p> <p>12 I am -- the only time I'm preparing 13 specifically for my own deposition is probably when I'm 14 reviewing another person's deposition. But that's also 15 not necessarily true because I'm correlating that to 16 medical records, so it gets complicated.</p> <p>17 Q. And, in terms of prior testimony, do you 18 remember yesterday we talked a little bit about whether 19 or not you were a biomaterials expert. And you said to 20 me, I would want to see that testimony, and I didn't 21 have it for you?</p> <p>22 A. Yes.</p> <p>23 Q. Do you still want to see it?</p> <p>24 A. If we want to continue that line of 25 questioning.</p>	<p style="text-align: right;">Page 747</p> <p>1 A. Well, again, it depends upon what we're 2 talking about as far as biomaterials expert. I do have 3 expertise, the papers I've written, both in animals and 4 in humans, studying them under the microscope, as we've 5 already mentioned today, so the mesh complications, 6 other medical devices and which are all biomaterials.</p> <p>7 So I do have a certain expertise in that 8 subject. Do I hold an advanced degree of Ph.D. in 9 biomaterials? The answer to that is, no. So, again, 10 it's not that the testimony is inconsistent. I'm 11 putting -- I'm describing it better.</p> <p>12 Q. Okay. And that is a better description. So 13 your testimony is from a clinician's perspective rather 14 than an advanced degree, biomaterials scientist; is that 15 a fair summary?</p> <p>16 A. I would agree with you with that, 17 yes.</p> <p>18 MS. GEIST: Okay. Dr. Elliott, I want to thank 19 you very much for your time and your patience. And I 20 don't have any further questions for you at this 21 time.</p> <p>22 THE WITNESS: Okay.</p> <p>23 CROSS-EXAMINATION</p> <p>24 BY MS. GAYLE:</p> <p>25 Q. Good afternoon, Dr. Elliott. I have some</p>
<p style="text-align: right;">Page 746</p> <p>1 Q. Well, I just want to know from you. I had 2 asked you yesterday if you were holding yourself out as 3 a biomaterials expert. And I had stated to you, with 4 all intention -- intentions of being accurate, that I 5 had read your prior testimony where you appeared as an 6 expert in the Ethicon Pelvic Mesh Litigation where you 7 had said, I'm not a biomaterials expert and you didn't 8 hold yourself out as a polymer chemist and things of 9 that nature. So I just want to make sure you're giving 10 the same testimony in this litigation as you did in that 11 litigation?</p> <p>12 MS. GAYLE: Object to form. His testimony from 13 yesterday is what it is.</p> <p>14 BY THE WITNESS:</p> <p>15 A. I put qualifiers on what I stated yesterday.</p> <p>16 I do not recall the Ethicon testimony word for word. I 17 don't know if Mr. Snell had put qualifiers on his 18 question. But I answered that, and I'll stand by my 19 answer as far as what the various different qualifiers I 20 put on there.</p> <p>21 Q. If you said, yeah, I'm not a biomaterials 22 expert, you have no reason to change that testimony and 23 say something different in this litigation, true?</p> <p>24 MS. GAYLE: Object to form.</p> <p>25 BY THE WITNESS:</p>	<p style="text-align: right;">Page 748</p> <p>1 follow-up questions. I'll try to make it as fast as we 2 can.</p> <p>3 A. Okay.</p> <p>4 Q. I know that we all have flights this evening. 5 If you'll turn back to meet with me to Exhibit 39 --</p> <p>6 A. Okay.</p> <p>7 Q. -- Bates number ending, I believe, with 8 DX0046-009?</p> <p>9 A. Yes.</p> <p>10 Q. 009 is the last three digits on the page, 11 Doctor?</p> <p>12 A. Okay. I'm there.</p> <p>13 Q. And, Doctor, do you remember your line of 14 questioning where counsel asked you various questions 15 over this packet of documents? Do you remember that 16 just moments ago?</p> <p>17 A. I remember well.</p> <p>18 Q. Okay. And I'm going to refer you to -- to a 19 statement. She referred you to BSC's response on this 20 particular page. Under the heading, Background, Doctor, 21 if you go three paragraphs down, okay?</p> <p>22 A. Okay. I'm there.</p> <p>23 Q. The paragraph starting in, However?</p> <p>24 A. Yes.</p> <p>25 Q. The last sentence of that paragraph, will you</p>

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<p style="text-align: right;">Page 749</p> <p>1 read that last sentence into the record, please?</p> <p>2 A. The agreement required Boston Scientific to be</p> <p>3 ultimately responsible for ensuring that the material is</p> <p>4 suites to the specific application and assume all</p> <p>5 product liability.</p> <p>6 Q. Doctor, with regard to Bard and the use of</p> <p>7 Marlex in its Avaulta Plus and Avaulta Solo products,</p> <p>8 have you ever seen where Bard has assumed responsibility</p> <p>9 for any product liability?</p> <p>10 MS. GEIST: Objection to form.</p> <p>11 BY THE WITNESS:</p> <p>12 A. In the documents I've reviewed, I have not</p> <p>13 read that, no.</p> <p>14 Q. In fact, Doctor, in the documents that you've</p> <p>15 reviewed, I believe that you testified that you actually</p> <p>16 had seen where Bard tried to hide the use of this</p> <p>17 Marlex; is that correct?</p> <p>18 MS. GEIST: Objection to form.</p> <p>19 BY THE WITNESS:</p> <p>20 A. I reviewed a series of e-mails where there was</p> <p>21 active attempts to hide how Bard was using the product,</p> <p>22 yes.</p> <p>23 Q. And let me just fix my question, Doctor, so I</p> <p>24 don't have any objections. Did Bard try to hide the use</p> <p>25 of Marlex in its Avaulta Plus product?</p>	<p style="text-align: right;">Page 751</p> <p>1 A. I reserve the right to supplement this report</p> <p>2 if new or supplemental information is provided at any</p> <p>3 point and as I review other related documents.</p> <p>4 Q. And, Doctor, I believe that you were asked a</p> <p>5 series of questions about whether or not you had</p> <p>6 reviewed the transcripts of treating physicians at the</p> <p>7 time that you had executed your report. Do you remember</p> <p>8 that line of questioning?</p> <p>9 A. I vaguely remember that, yes.</p> <p>10 Q. And should available information or</p> <p>11 transcripts become available to you, would you be</p> <p>12 willing to review those, Doctor?</p> <p>13 A. I would want --</p> <p>14 MS. GEIST: Objection. Form. You can answer,</p> <p>15 Doctor.</p> <p>16 BY THE WITNESS:</p> <p>17 A. Okay. No. I would want to review -- if</p> <p>18 documents become available, whether they be medical</p> <p>19 transcripts, depositions, any new information that shed</p> <p>20 light on this subject, I would be very willing to read</p> <p>21 those.</p> <p>22 Q. And if your opinions change, Doctor, then</p> <p>23 would you issue an amended report?</p> <p>24 A. Well, I keep an open mind. And if an amended</p> <p>25 report is required or needed or helpful, then we would</p>
<p style="text-align: right;">Page 750</p> <p>1 MS. GEIST: Objection to form, inferring Bard's</p> <p>2 intent from company documents.</p> <p>3 BY THE WITNESS:</p> <p>4 A. The e-mails that I reviewed stated, and we can</p> <p>5 pull those out and state them if you'd like, but,</p> <p>6 ultimately, multiple times do not let the company -- do</p> <p>7 not let Phillips Sumika -- Sumika know that we are doing</p> <p>8 this. Do not -- do not -- make sure they do not have</p> <p>9 that information.</p> <p>10 Q. So they weren't forthcoming with that</p> <p>11 information, correct, Doctor?</p> <p>12 MS. GEIST: Objection to form, infers Bard's intent</p> <p>13 from company documents.</p> <p>14 BY THE WITNESS:</p> <p>15 A. All I can go off is that series of e-mails</p> <p>16 where it does not take an M.D. or a Ph.D. It is very</p> <p>17 clear to anybody what their intent was.</p> <p>18 Q. Let's go down to Ms. Bolyard's report now,</p> <p>19 Doctor, Exhibit 35. And I'm just going to kind of go</p> <p>20 back, backwards, if you don't mind.</p> <p>21 A. Okay.</p> <p>22 Q. Doctor, if you turn to the first page of</p> <p>23 Exhibit 35, the first paragraph, can you read into the</p> <p>24 record the first sentence -- the last sentence of that</p> <p>25 first paragraph, Doctor, starting with, I reserve?</p>	<p style="text-align: right;">Page 752</p> <p>1 do that.</p> <p>2 Q. And do you know, at the time of your report,</p> <p>3 Doctor, whether or not the transcripts for those</p> <p>4 treaters were available to you?</p> <p>5 A. I don't know that.</p> <p>6 MS. GEIST: Objection to form.</p> <p>7 BY MS. GAYLE:</p> <p>8 Q. And, Doctor, I think on Ms. Bolyard you were</p> <p>9 also asked a series of questions with regard to her</p> <p>10 sexual status. Do you remember that line of</p> <p>11 questioning?</p> <p>12 A. In general, yes.</p> <p>13 Q. Do you remember the questions about her</p> <p>14 husband who suffered from erectile dysfunction?</p> <p>15 A. Yes.</p> <p>16 Q. Doctor, in your experience and practice, is it</p> <p>17 possible that a woman be engaging in physical intimacy</p> <p>18 with her husband if he has erectile dysfunction?</p> <p>19 MS. GEIST: Objection to form.</p> <p>20 BY THE WITNESS:</p> <p>21 A. Oh, it's possible, yes.</p> <p>22 Q. And, in fact, that condition would not keep --</p> <p>23 prohibit him completely from having intimate -- intimacy</p> <p>24 with his wife, would it?</p> <p>25 MS. GEIST: Objection to form.</p>

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<p>1 BY THE WITNESS:</p> <p>2 A. By no means. I'm a urologist. As compared to</p> <p>3 a gynecologist who only sees women, I also see men.</p> <p>4 25 -- 25 percent of my practice is male. So we are</p> <p>5 treating impotence. Impotence in and of itself does not</p> <p>6 inhibit sexual activity. It may make it a little more</p> <p>7 difficult, but there are treatments available.</p> <p>8 Q. And, likewise, Doctor, if, for some reason, as</p> <p>9 counsel had inferred that his erectile dysfunction was</p> <p>10 completely inhibiting him from having sex, then that</p> <p>11 doesn't mean that the couple could not be having sex</p> <p>12 through other methods, including, perhaps, the use of a</p> <p>13 dildo, correct?</p> <p>14 MS. GEIST: Objection to form.</p> <p>15 BY THE WITNESS:</p> <p>16 A. As a urologist dealing with pelvic floor,</p> <p>17 there are a lot of different ways to have intercourse.</p> <p>18 MS. GEIST: I'm going to object to this whole line</p> <p>19 of questioning.</p> <p>20 MS. GAYLE: You brought it up, Counsel. You</p> <p>21 inferred they weren't having sex. And so I apologize I</p> <p>22 have to go through for everybody in the room.</p> <p>23 MS. GEIST: I did not say anything about a dildo.</p> <p>24 Lord knows I did not.</p> <p>25</p>	<p>Page 753</p> <p>1 a lot of questions over two days, so I don't remember.</p> <p>2 I mean, I remember in generality.</p> <p>3 Q. Sure. So let's just break it down for you,</p> <p>4 Doctor. When you spoke with Ms. Wheeler, did you</p> <p>5 measure her dyspareunia on the VAS scale?</p> <p>6 MS. GEIST: Objection to form.</p> <p>7 BY THE WITNESS:</p> <p>8 A. Yes. I used the Visual Analog Pain Scale and</p> <p>9 current situation. If sexual activity were to take</p> <p>10 place -- she graded it, not I -- she graded it as an 8.</p> <p>11 Q. And, Doctor, have you found that that VAS</p> <p>12 scale is a reliable instrument of measure?</p> <p>13 A. Yes.</p> <p>14 Q. Measurement?</p> <p>15 MS. GEIST: Objection to form.</p> <p>16 BY THE WITNESS:</p> <p>17 A. There have been multiple studies that the</p> <p>18 Visual Analog Scale is highly reproducible for an</p> <p>19 individual.</p> <p>20 Q. And, Doctor, I believe, if you also turn to</p> <p>21 the first page -- just one moment. Let me make sure I'm</p> <p>22 on Wheeler. Doctor, turn to page 3 of Ms. Wheeler's</p> <p>23 report, if you would.</p> <p>24 A. I'm there.</p> <p>25 Q. And I believe there was discussion going back</p>
<p>1 BY MS. GAYLE:</p> <p>2 Q. Doctor, there's other ways that couples can</p> <p>3 engage in sexual relations; isn't that correct, other</p> <p>4 than penetration?</p> <p>5 A. There is a lot of different ways that sexual</p> <p>6 activity can take place.</p> <p>7 Q. Thank you, Doctor. And, Doctor, with regard</p> <p>8 to all three of the questions and in the interest of</p> <p>9 time, you performed differential -- differential</p> <p>10 diagnosis for all three ladies as we've -- as you've</p> <p>11 discussed today, correct?</p> <p>12 A. Correct.</p> <p>13 MS. GEIST: Objection. Asked and answered.</p> <p>14 BY MS. GAYLE:</p> <p>15 Q. And, Doctor, I'm going to skip over to</p> <p>16 Ms. Wheeler now. You can grab hers, and I don't exactly</p> <p>17 have which number that was.</p> <p>18 A. I have Wheeler's, No. 33.</p> <p>19 Q. Yes. Thank you. You were asked a series of</p> <p>20 questions about her degree of dyspareunia. I believe</p> <p>21 counsel quoted to you that it was a lesser degree of</p> <p>22 dyspareunia in the records than the more severe degree</p> <p>23 that Ms. Wheeler discussed with you. Do you remember</p> <p>24 that line of questioning earlier today?</p> <p>25 A. Actually, I do not remember it. There's been</p>	<p>Page 754</p> <p>1 and forth, and it could have been Ms. Alonso. But just</p> <p>2 for the record to clarify, first paragraph, Ms. Wheeler</p> <p>3 had the Solo posterior and Solo anterior, correct?</p> <p>4 A. Correct.</p> <p>5 Q. And Ms. Alonso, can you turn to hers? And it</p> <p>6 might be around exhibit -- do you have it?</p> <p>7 A. Yes, I do.</p> <p>8 Q. And, similarly, can you tell me what product</p> <p>9 she had, Doctor?</p> <p>10 A. According to my records, she had an Avaulta</p> <p>11 anterior and the Align transobturator sling.</p> <p>12 Q. And, Doctor, if it were the product that had</p> <p>13 the Avaulta Plus, then I think you testified earlier or</p> <p>14 at some point today that a patient would be at a higher</p> <p>15 risk than if it would have been the Avaulta Solo,</p> <p>16 correct?</p> <p>17 MS. GEIST: Objection to form. Higher risk of</p> <p>18 what?</p> <p>19 MS. GAYLE: Higher risk of complications.</p> <p>20 MS. GEIST: Objection to form.</p> <p>21 BY THE WITNESS:</p> <p>22 A. There is data available demonstrating, from</p> <p>23 internal documents, external reviews, manuscripts, that,</p> <p>24 when the collagen is implanted, then there's increased</p> <p>25 hypersensitivity and decreased healing with the Avaulta</p>

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<p style="text-align: right;">Page 757</p> <p>1 Plus.</p> <p>2 Q. And, Doctor, with regard to each of the three 3 ladies, you were asked a series of questions about the 4 implantation methods. So I'm going to break it down. 5 With regard to Ms. Alonso, did you see 6 anything that was outside the standard of care in her 7 implantation of mesh?</p> <p>8 MS. GEIST: Objection to form.</p> <p>9 BY THE WITNESS:</p> <p>10 A. No.</p> <p>11 Q. And the same question for Ms. Wheeler. 12 Doctor, did you see anything outside the standard of 13 care for the implantation of her Avaulta devices or 14 Align device?</p> <p>15 A. In review of the --</p> <p>16 MS. GEIST: Objection to form. Asked and answered. 17 You can go ahead, Doctor.</p> <p>18 BY THE WITNESS:</p> <p>19 A. In the review of the operative note, I did not see anything that stated it was outside the standard of care.</p> <p>22 Q. And the same question for Ms. Bolyard?</p> <p>23 A. Same answer, review of the surgical operative note, I saw nothing outside the standard of care.</p> <p>25 Q. And, Doctor, again, let's go back to each one</p>	<p style="text-align: right;">Page 759</p> <p>1 BY THE WITNESS: 2 A. No. 3 Q. That includes smoking on behalf of Ms. Bolyard 4 as well, Doctor? 5 MS. GEIST: Same objection. 6 BY THE WITNESS: 7 A. Yeah. We went over that earlier. I saw 8 nothing in there that her history of smoking led to her 9 product complication. 10 Q. And, Doctor, I think that you, early in 11 this day, were asked a series of questions and 12 counsel had inferred that you had gotten rid of your 13 notes. 14 Is your process, as I understood it, is your 15 process an evolution where you go from a notepad to a 16 Word document and that Word document evolves into your 17 eventual final product? 18 MS. GEIST: Objection to form. Asked and answered. 19 We went over this a long time. And objection to any 20 statement about what I was inferring. 21 BY THE WITNESS: 22 A. Correct. I agree with you. 23 MS. GAYLE: Okay. Okay. All right. We're done. 24 Thank you, Doctor. 25 MS. GEIST: Thank you, Doctor.</p>
<p style="text-align: right;">Page 758</p> <p>1 of these three questions or three cases with regard to 2 particular activities of the lady. 3 With regard to Ms. Alonso, did you say that 4 she engaged in sexual activity in a way that would have 5 caused her complications? In other words, prematurely 6 engaged in sexual activity? 7 MS. GEIST: Objection to form. 8 BY THE WITNESS: 9 A. I saw nothing in the records that she 10 was engaged in sexual activity too early or anything 11 that would predispose her to failure or 12 complications. 13 Q. And did you see anything in the records or 14 learn anything regarding Ms. Wheeler that would 15 indicate that she engaged in sexual activities 16 prematurely? 17 A. Same answer. I saw nothing in the records to 18 support that. 19 Q. And same questions for Ms. Bolyard? 20 A. And same answer. I saw nothing in the 21 records. 22 Q. Did you see anything in the records that would 23 predispose any of these women to have caused their own 24 complications from these products? 25 MS. GEIST: Objection to form. Asked and answered.</p>	<p style="text-align: right;">Page 760</p> <p>1 VIDEO TECHNICIAN: This concludes today's 2 deposition of Dr. Daniel Elliot. We're off the record. 3 The time is 3:41 p.m. 4 (Witness excused.) 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25</p>

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<p>1 UNITED STATES OF AMERICA) 2 NORTHERN DISTRICT OF ILLINOIS) 3 EASTERN DIVISION) SS. 4 STATE OF ILLINOIS) 5 COUNTY OF COOK)</p> <p>5 I, Jennifer L. Bernier, Certified Shorthand 6 Reporter, Registered Professional Reporter, and Notary 7 Public, do hereby certify that DANIEL S. ELLIOT, M.D., 8 was first duly sworn by me to testify to the whole truth 9 and that the above deposition was reported 10 stenographically by me and reduced to typewriting under 11 my personal direction.</p> <p>12 I further certify that the said deposition was 13 taken at the time and place specified and that the 14 taking of said deposition commenced on November 15 and 15 16th, 2014.</p> <p>16 I further certify that I am not a relative or 17 employee or attorney or counsel of any of the parties, 18 nor a relative or employee of such attorney or counsel, 19 nor financially interested directly or indirectly in 20 this action.</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: center;">Page 761</p> <p>1 TO: Daniel Elliott M.D., Vol. II 2 Re: Reading and Signing Your Deposition Transcript 3 Date Errata due back at our offices: 12/20/2014 4 5 Greetings: 6 You have reserved the right to read and sign your 7 deposition transcript. Please review the attached 8 PDF transcript, noting any changes or corrections 9 on the attached PDF Errata. You may fill out the 10 Errata electronically or print and fill out manually. 11 12 The PDF files open with Adobe Reader. If you need help 13 opening these files, please see the instructions in the 14 cover letter of this email. 15 16 Once you have completed your Errata, please print it, sign 17 it, and have the document notarized in the place provided. 18 19 When the signed Errata is returned to us, we will seal 20 and forward to the taking attorney to file with the 21 original transcript. We will also send copies of the 22 Errata to all ordering parties. 23 24 If the signed Errata is not returned within the time 25 below, the original transcript may be filed with the 26 court without your signature. 27 28 Please send completed Errata to: 29 Tiffany Alley Global Reporting & Video 30 730 Peachtree St. NE, Ste 470 31 Atlanta, GA 30308 32 (770) 343-9696</p> <p style="text-align: center;">Page 763</p> <p>1 ERRATA 2 I, the undersigned, do hereby certify that I have read the 3 transcript of my testimony, and that 4 _____ There are no changes noted. 5 _____ The following changes are noted: 6 7 Pursuant to Rule 30(7)(e) of the Federal Rules of Civil 8 Procedure and/or OCGA 9-11-30(e), any changes in form or 9 substance which you desire to make to your testimony shall 10 be entered upon the deposition with a statement of the 11 reasons given for making them. To assist you in making any 12 such corrections, please use the form below. If additional 13 pages are necessary, please furnish same and attach. 14 15 Page _____ Line _____ Change _____ 16 17 Reason for change _____ 18 Page _____ Line _____ Change _____ 19 20 Reason for change _____ 21 Page _____ Line _____ Change _____ 22 23 Reason for change _____ 24 Page _____ Line _____ Change _____ 25 Reason for change _____</p> <p style="text-align: center;">Page 764</p>
<p>1 In witness whereof, I have hereunto set my 2 hand and affixed my seal of office at Chicago, Illinois, 3 this 5th day of November, A.D., 2014.</p> <p>4</p> <p>5</p> <p>6</p> <p>7</p> <p style="text-align: center;"></p> <p>8 JENNIFER L. BERNIER, CSR, RPR, CLR 9 CSR No. 084-004190</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p>1 ERRATA 2 I, the undersigned, do hereby certify that I have read the 3 transcript of my testimony, and that 4 _____ There are no changes noted. 5 _____ The following changes are noted: 6 7 Pursuant to Rule 30(7)(e) of the Federal Rules of Civil 8 Procedure and/or OCGA 9-11-30(e), any changes in form or 9 substance which you desire to make to your testimony shall 10 be entered upon the deposition with a statement of the 11 reasons given for making them. To assist you in making any 12 such corrections, please use the form below. If additional 13 pages are necessary, please furnish same and attach. 14 15 Page _____ Line _____ Change _____ 16 17 Reason for change _____ 18 Page _____ Line _____ Change _____ 19 20 Reason for change _____ 21 Page _____ Line _____ Change _____ 22 23 Reason for change _____ 24 Page _____ Line _____ Change _____ 25 Reason for change _____</p>

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DEPONENT'S SIGNATURE

21 Sworn to and subscribed before me this ____ day of
22 _____, _____.
23 _____

24 NOTARY PUBLIC
25 My Commission Expires: _____

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